



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

# Medical Devices – Essential Principles for Safety and Performance

Attachment 1: Proposals to align the Australian Essential Principles with the European General Safety and Performance Requirements

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## About

This attachment presents each clause of the Australian (AUS) Essential Principles against the equivalent EU GSPRs together with the proposed changes for alignment. A summary of our approach to the alignment is below:

- **No change:** Where we consider the intent of the EU GSPR and AUS Essential Principle to be aligned.
- **Clarify:** Where the EU GSPR provides clarification on the expectation of compliance, we propose to provide equivalent additional information.
- **NEW clause** (within an AUS Essential Principle): Where the EU GSPR has additional requirements that we consider would improve safety or performance, we propose to align.
- **NEW Essential Principle:** Where we have no equivalent AUS Essential Principle to the EU GSPR and we consider the requirement would improve safety or performance, we propose to align.
- **AUS-specific proposal:** Where we consider additional clarity is required for safety or performance.

The proposed changes will align with the intent of the EU GSPR. However, the legislative wording may differ due to difference in legislative structure between Europe and Australia.



# New AUS Essential Principles

## Proposal 1: Adopt new AUS Essential Principles

We propose to adopt the intent of each of the EU GSPRs in the table below which apply to both IVDs and all other medical devices.

There are currently no AUS Essential Principles that align with the intent of the EU GSPRs in this section, except for IVDR GSPR 19, which partly aligns with requirements of AUS Essential Principle 15.

EU Reference	EU GSPR Text	Proposal 1 - Intent and <i>comments</i>
MDR GSPR 2 IVDR GSPR 2	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio	<p><b>Proposal 1(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"><li>• Introduce the intent of GSPR 2 to clarify the expectations for reducing or minimising risk as far as possible, including introducing the term benefit-risk ratio.</li></ul> <p><b>AUS-specific</b></p> <ul style="list-style-type: none"><li>• Include reference to the AUS Essential Principle 2, in addition to alignment with EU GSPR 2, regarding the expectations in reducing or minimising risk as far as possible.</li></ul> <p><i>AUS Essential Principle 2 provides a priority order in which the manufacturer must select appropriate solutions for the design and construction of a medical device to minimise any risks associated with the use of the device. As such, in creating an Essential Principle to align with EU GSPR 2, we consider it important to additionally include reference to the requirements of AUS Essential Principle 2.</i></p>

EU Reference	EU GSPR Text	Proposal 1 - Intent and <i>comments</i>
MDR GSPR 3 IVDR GSPR 3	<p>Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:</p> <ul style="list-style-type: none"> <li>(a) Establish and document a risk management plan for each device;</li> <li>(b) Identify and analyse the known and foreseeable hazards associated with each device;</li> <li>(c) Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;</li> <li>(d) Eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;</li> <li>(e) Evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and</li> <li>(f) Based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4</li> </ul>	<p><b>Proposal 1(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Introduce the intent of EU GSPR 3 to require manufacturers to establish, implement, document and maintain a risk management system, with equivalent expectations as detailed in EU GSPR 3.</li> </ul>
MDR GSPR 5 IVDR GSPR 5	<p>In eliminating or reducing risks related to user error, the manufacturer shall:</p> <ul style="list-style-type: none"> <li>(a) Reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and</li> <li>(b) Give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay person, professional, disabled or other users).</li> </ul>	<p><b>Proposal 1(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Introduce the intent for manufacturers to eliminate or reduce risks related to errors in use of their device, including minimising risks related to ergonomic features of the device and the environment in which it is intended to be used, with consideration being given to</li> </ul>

EU Reference	EU GSPR Text	Proposal 1 - Intent and <i>comments</i>
		potential differences in abilities of the intended user.
<b>MDR GSPR 22</b>	<p><b>Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons.</b></p> <p>22.1 Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.</p> <p>22.2.Devices for use by lay persons shall be designed and manufactured in such a way as to:</p> <ul style="list-style-type: none"> <li>– Ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,</li> <li>– Reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and</li> <li>– Reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.</li> </ul> <p>22.3.Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:</p> <ul style="list-style-type: none"> <li>– Can verify that, at the time of use, the device will perform as intended by the manufacturer, and</li> <li>– If applicable, is warned if the device has failed to provide a valid result.</li> </ul>	<p><b>Proposal 1(a) NEW</b></p> <p><b>For all devices intended for use by lay persons:</b></p> <ul style="list-style-type: none"> <li>• Devices intended for use by lay persons, be design and produce to perform as intended by the manufacturer, considering and applying the details outlined in EU GSPR 22.</li> </ul> <p><b>AUS-specific:</b></p> <ul style="list-style-type: none"> <li>• Apply MDR GSPR 22 to <b>IVD devices</b>.</li> </ul> <p><i>The EU address equivalent requirements separately for IVD devices, under EU IVDR GSPR 19. In aligning with the intent of EU MDR GSPR 22, our intent is to apply the adopted requirement to all devices intended to be used by lay persons.</i></p> <p><i>Given the requirements closely align with those for IVD devices included, or proposed, under AUS Essential Principle 15, the final legislative structure may reduce any duplication.</i></p>

## General AUS Essential Principles 1, 3, 5, 6: No changes proposed

We consider AUS Essential Principle 1, 3, 5 and 6 to be aligned in intent with the equivalent European GSPRs. No changes are proposed.

AUS Essential Principle	EU MDR	EU IVDR
<p><b>EP 1 Use of medical devices not to compromise health and safety</b></p> <p>A medical device is to be designed and produced in a way that ensures that:</p> <ul style="list-style-type: none"> <li>(a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and</li> <li>(b) any risks associated with the use of the device are: <ul style="list-style-type: none"> <li>(i) acceptable risks when weighed against the intended benefit to the patient; and</li> <li>(ii) compatible with a high level of protection of health and safety.</li> </ul> </li> </ul>	<p><b>GSPR 1</b></p> <p>Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.</p>	
<p><b>EP 3 Medical devices to be suitable for intended purpose</b></p> <p>The medical device must:</p> <ul style="list-style-type: none"> <li>(a) perform in a way intended by the manufacture; and</li> <li>(b) be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of medical device in subsection 41BD(1) of the Act.</li> </ul>		
<p><b>EP 5 Medical devices not to be adversely affected by transport or storage</b></p>	<p><b>GSPR 7</b></p> <p>Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are</p>	



AUS Essential Principle	EU MDR	EU IVDR
<p>A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer.</p>	<p>not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.</p>	
<p><b>EP 6 Benefits of medical devices to outweigh any undesirable effects</b></p> <p>The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.</p>	<p><b>GSPR 8</b></p> <p>All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.</p>	<p><b>GSPR 8</b></p> <p>All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use.</p>

## General AUS Essential Principles 2 and 4

AUS Essential Principle 2	EU MDR	EU IVDR	Proposal 2 - Intent and <i>comments</i>
<p><b>EP 2 Design and construction of medical devices to conform with safety principles</b></p> <p>(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.</p>	<p><b>GSPR 4</b> Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art.</p> <p>To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.</p> <p>In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:</p>		<p><b>Proposal 2(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>To clarify that “information for safety” would be expected to include warnings, precautions, and contra-indications, as described in the EU GSPR 4.</li> </ul>

AUS Essential Principle 2	EU MDR	EU IVDR	Proposal 2 - Intent and <i>comments</i>
<p>(2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:</p> <p>(a) First, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and</p> <p>(b) Second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and</p> <p>(c) Third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and</p> <p>(d) Fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.</p> <p>(3) In paragraph 2(d): residual risk, for a medical device, means the risk remaining after the measures</p>	<p>Eliminate or reduce risks as far as possible through safe design and manufacture;</p> <p>Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and</p> <p>Provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.</p> <p>Manufacturers shall inform users of any residual risks.</p>		

AUS Essential Principle 2	EU MDR	EU IVDR	Proposal 2 - Intent and <i>comments</i>
described in paragraphs (2)(a), (b) and (c) have been applied.			
<p><b>EP 4 Long-term safety</b></p> <p>A medical device must be designed and produced in a way that ensures that if:</p> <ul style="list-style-type: none"> <li>(a) The device is used within the period, indicated by the manufacturer, in which the device can be safely used; and</li> <li>(b) The device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and</li> <li>(c) The device is regularly maintained and calibrated in accordance with the manufacturer's instructions;</li> </ul> <p>The characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.</p>	<p><b>MDR GSPR 6</b> The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.</p>	<p><b>IVDR GSPR 9.2</b> The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.</p>	<p><b>Proposal 2(b)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• To clarify the expectation that manufactures are to design and produce a device so that the characteristics and performance are maintained throughout the lifetime of the device, as described in EU GSPR 6/IVDR GSPR 9.2.</li> </ul>

## Design and construction: AUS Essential Principles 7 – 12 and 15

### Proposal 3: AUS Essential Principle 7 – Chemical, physical and biological properties

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
<p><b>EP 7 Chemical, physical and biological properties</b></p> <p><b>EP 7.1 Choice of materials</b></p> <p>In ensuring that the requirements of Part 1 are met in relation to a medical device,</p> <p>Particular attention must be given to:</p> <p>(a) Chemical and physical properties used in the device; and</p> <p>(b) The compatibility between the materials used and biological tissues, cells, body fluids and specimens;</p> <p>Having regard to the intended purpose of the device.</p>	<p><b>GSPR 10 Chemical, physical and biological properties</b></p> <p><b>GSPR 10.1</b> Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.</p> <p>Particular attention shall be paid to:</p> <p>(a) The choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;</p> <p>(b) The compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;</p> <p>(c) The compatibility between the different parts of a device which consists of more than one implantable part;</p>	<p><b>GSPR 10 Chemical, physical and biological properties</b></p> <p><b>GSPR 10.1</b> Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled.</p> <p>Particular attention shall be paid to:</p> <p>The possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.</p>	<p>Proposal 3(a)</p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Increase clarity on factors to be considered, related to choice of materials, by adopting the intent of the requirements in EU MDR GSPR 10.1 (a-h), with particular attention being paid to: <ul style="list-style-type: none"> <li>(a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;</li> <li>(b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;</li> <li>(c) the compatibility between the different parts of a device which consists of more than one implantable part;</li> </ul> </li> </ul>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
	<p>(d) The impact of processes on material properties;</p> <p>(e) Where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;</p> <p>(f) The mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;</p> <p>(g) Surface properties; and</p> <p>(h) The confirmation that the device meets any defined chemical and/or physical specifications.</p>		<p>(d) the impact of processes on material properties;</p> <p>(e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;</p> <p>(f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;</p> <p>(g) surface properties; and</p> <p>(h) the confirmation that the device meets any defined chemical and/or physical specifications.</p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Provide clarity by including the details in IVDR GSPR 10.1 for which particular attention should be paid including, but not limited to, the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells,</li> </ul>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
			body fluids and micro-organisms), taking account of the intended purpose of the device.
	<p data-bbox="689 400 1106 432">No equivalent EU GSPR in IVDR.</p> <p data-bbox="689 448 1624 576"><b>MDR GSPR 12.2</b> Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.</p> <ul data-bbox="712 592 1624 911" style="list-style-type: none"> <li>– Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.</li> </ul>		<p data-bbox="1639 408 1816 440"><b>Proposal 3(a)</b></p> <p data-bbox="1639 464 1917 496"><b>For non-IVD devices:</b></p> <ul data-bbox="1639 520 2096 1294" style="list-style-type: none"> <li>• Provide clarity that for devices composed of substances, or of combinations of substances, that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body, that attention be paid to the evaluation of: <ul style="list-style-type: none"> <li>– absorption</li> <li>– distribution</li> <li>– metabolism</li> <li>– excretion</li> <li>– local tolerance</li> <li>– toxicity</li> <li>– interaction with other devices, medicinal products or other substances</li> <li>– potential for adverse reactions.</li> </ul> </li> </ul>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
<p><b>EP 7.2 Minimisation of risks associated with contaminants and residues</b></p> <p>(1) A medical device must be designed, produced, and packed in a way that ensures that any risks associated with contaminants and residues that may affect a person who is involved in transporting, storing, or using the device, or a patient, are minimised, having regard to the intended purpose of the device.</p> <p>(2) In minimising risks, particular consideration must be given to the likely duration and frequency of any tissue exposure associated with the transportation, storage or use of the device.</p>	<p><b>MDR GSPR 10.2 and IVDR GSPR 10.2</b></p> <p>Devices shall be designed, manufactured, and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices.</p> <p>Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.</p>		<p>No proposed change.</p>
<p><b>EP 7.3 Ability to be used safely with materials etc</b></p> <p>(1) A medical device must be designed and produced in a way that ensures that the device can be used safely with any material, substance or gas with which the device may come into contact during normal use or use in routine procedures.</p>	<p><b>No equivalent EU GSPR in IVDR.</b></p> <p><b>MDR GSPR 10.3</b></p> <p>Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use;</p> <p>If the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to:</p>		<p>No proposed change.</p>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
<p>(2) If the device is intended to be used to administer medicine, it must be designed and produced in a way that ensures that the device:</p> <p>(a) Is compatible with the provisions and restrictions applying to the medicine to be administered; and</p> <p>(b) Allows the medicine to perform as intended.</p>	<ul style="list-style-type: none"> <li>– Be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and</li> <li>– That the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.</li> </ul>		
<p><b>EP 7.4 Verification of incorporated substance</b></p> <p>(1) If a medical device incorporates, or is intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device:</p> <p>(a) The safety and quality of the substance must be verified in accordance with the requirements for medicines; and</p> <p>(b) The ancillary action of the substance must be verified having regard to the intended purpose of the device.</p>	<p><b>No equivalent EU GSPR in IVDR.</b></p> <p><b>MDR GSPR 12</b> Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.</p> <p><b>GSPR 12.1</b> In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC**, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC***, as required by the applicable conformity assessment procedure under this Regulation.</p> <p><b>GSPR 12.2</b> Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.</p> <p>Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply,</p>		<p>No proposed change.</p>



AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
(2) For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine.	where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.		
<p><b>EP 7.5 Minimisation of risks associated with leaching substances</b></p> <p>A medical device must be designed and produced in a way that ensures that any risks associated with substances that may leach from the device are minimised.</p>	<p><b>GSPR 10.4 Substances</b></p> <p><b>GSPR 10.4.1. Design and manufacture of devices</b></p> <p>Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.</p> <p>Devices, or those parts thereof or those materials used therein that:</p> <ul style="list-style-type: none"> <li>– Are invasive and come into direct contact with the human body,</li> <li>– (re)administer medicines, body liquids or other substances, including gases, to/from the body, or</li> <li>– Transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,</li> </ul>	<p><b>GSPR 10 Chemical, physical and biological properties</b></p> <p><b>GSPR 10.3</b> Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.</p> <p>Special attention shall be given to substances which are:</p> <ul style="list-style-type: none"> <li>– Carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), and</li> <li>– To substances having endocrine disrupting properties for which there is scientific evidence of</li> </ul>	<p><b>Proposal 3(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• <b>NEW:</b> Expand the scope to include leaching of <b>particles</b></li> <li>• Clarify that leaching and release of substances includes wear debris, degradation products and processing residues, that may be released from the device.</li> <li>• <b>NEW:</b> Special attention shall be given to minimising risks as far as possible associated leaking or leaching of: <ul style="list-style-type: none"> <li>– substances which are known to be carcinogenic, mutagenic or toxic to reproduction ('CMR') and</li> <li>– substances which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health.</li> </ul> </li> </ul>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
	<p>shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:</p> <p>(a) Substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or</p> <p>(b) Substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article</p>	<p>probable serious effects to human health and</p> <p>– Which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>1</sup></p>	<p><i>As Australia does not have the equivalent legislative framework as Europe regarding the requirements placed on CRM and/or endocrine-disrupting substances, we will at this stage, propose to take a broader principles-approach. This will be similar to that outlined in the IMDRF guidelines. As such, the specific requirements of EU MDR GSPR 10.4.1, 10.4.2 and 10.4.5 will not be adopted.</i></p> <p><i>However, we may include in our guidance clarification on applying the principles of EP2 in minimising risks related to such substances. For example, it would be expected that for any substances known to be carcinogenic, mutagenic or toxic to reproduction, or endocrine-disrupting, the manufacturer would:</i></p> <ul style="list-style-type: none"> <li><i>– undertake an analysis and estimation of potential patient or user exposure to the substance</i></li> <li><i>– undertake an analysis of possible alternative substances, materials</i></li> </ul>

<sup>1</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
	5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.		<p><i>or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives</i></p> <ul style="list-style-type: none"> <li><i>– be able to justify as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials.</i></li> <li><i>– Include precautions and warnings for any vulnerable populations for which the device is intended to be used.</i></li> </ul>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in IVDR. <b>MDR GSPR 10.4.2 Justification regarding the presence of CMR and/or endocrine-disrupting substances</b>		No proposed change.

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
	<p>The justification for the presence of such substances shall be based upon:</p> <ul style="list-style-type: none"> <li>(a) an analysis and estimation of potential patient or user exposure to the substance;</li> <li>(b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;</li> <li>(c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and</li> <li>(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. And 10.4.4.</li> </ul>		
<p>No equivalent AUS Essential Principle.</p>	<p>No equivalent EU GSPR in IVDR.</p> <p><b>MDR GSPR 10.4.3 Guidelines on phthalates</b></p> <p><b>MDR GSPR 10.4.4 Guidelines on other CMR and endocrine-disrupting substances</b></p>		<p>No proposed change.</p> <p><i>These requirements apply to the EU Commission to publish guidance. Our AUS Essential Principles only apply to manufacturers.</i></p>
<p>No equivalent AUS Essential Principle.</p>	<p>No equivalent EU GSPR in IVDR.</p> <p><b>MDR GSPR 10.4.5 Substances - Labelling</b></p> <p>Where devices, parts thereof or materials used therein as referred to in Section 10.4.1 contain substances referred to in points (a) or (b) of Section 10.4.1 in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or</p>		<p>No proposed change.</p> <p><i>Refer to comments under AUS EP 7.5 related to EU MDR GSPR 10.4.1.</i></p>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
		on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.	
<p><b>EP 7.6 Minimisation of risks associated with ingress or egress of substances</b></p> <p>A medical device must be designed and produced in a way that ensures that any risks associated with unintentional ingress of substances into, or unintentional egress of substances out of, the device are minimised, having regard to the nature of the environment in which the device is intended to be used.</p>		<p><b>MDR GSPR 10.5 and IVDR GSPR 10.4</b></p> <p>Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.</p>	<p><b>Proposal 3(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• AUS Essential Principles 7.5 and 7.6 to be restructured so that the ingress requirements are within one clause and the requirements for egress and leaching are combined within a separate clause.</li> </ul>
<p><b>EP 7.7 Minimisation of risks associated with nanomaterials</b></p> <p>(1) A medical device must be designed and produced in a way that ensures that any risks associated with the size and the properties of particles which are, or can be, released into a patient's or user's body are minimised.</p>		<p><b>No equivalent EU GSPR in IVDR.</b></p> <p><b>MDR GSPR 10.6</b> Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.</p>	<p>No proposed change.</p>

AUS Essential Principle 7	EU MDR	EU IVDR	Proposal 3 - Intent and <i>comments</i>
<p>(2) In minimising risks, particular attention must be given to the use of nanomaterials.</p> <p>(3) Subclause (1) does not apply to particles that come into contact with intact skin only.</p>			

## Proposal 4: AUS Essential Principle 8 – Infection and microbial contamination

AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
<p><b>EP 8 Infection and microbial contamination</b></p> <p><b>EP 8.1 Minimisation of risk and contamination</b></p> <p>(1) A medical device must be designed and produced in a way that ensures that the risk of infection to a patient, a user, or any other person, is eliminated or minimised.</p> <p>(2) The device must be designed in a way that:</p> <p>(a) Allows it to be easily handled; and</p> <p>(b) If appropriate, minimises contamination of the device or specimen by the patient, user or other person; and</p> <p>(c) If appropriate, minimises contamination of the patient,</p>	<p><b>GSPR 11 Infection and microbial contamination</b></p> <p><b>GSPR 11.1</b> Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:</p> <p>(a) Reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,</p> <p>(b) Allow easy and safe handling,</p> <p>(c) Reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and</p>	<p><b>GSPR 11 Infection and microbial contamination</b></p> <p><b>GSPR 11.1</b> Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall:</p> <p>(a) Allow easy and safe handling;</p> <p>(b) Reduce as far as possible any microbial leakage from the device and/or microbial exposure during use;</p> <p>(c) Where necessary, prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.</p>	<p><b>Proposal 4(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Clarify the intent that, where applicable, the risks of unintended cuts and pricks is to be minimised</li> <li>Require devices to be designed to allow safe handling.</li> </ul> <p><i>The intent of MDR (c) and IVDR (b) are already aligned with AUS Essential Principle 8.1(c)</i></p> <p><i>The intent of MDR (d) and of IVDR (c) are already aligned with AUS Essential Principle 8.1(b).</i></p>

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user or other person by the device or specimen.	(d) Prevent microbial contamination of the device or its content such as specimens or fluids.		
No equivalent AUS Essential Principle.	<p><b>13. Devices incorporating materials of biological origin</b></p> <p><b>GSPR 13.1</b> For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:</p> <p>(a) Donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;</p> <p>(b) Processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated</p>		<p>No proposed changes.</p> <p><i>Not being adopted, as this requirement lies outside of our medical device regulatory framework.</i></p>

AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
	<p>methods of elimination or inactivation in the course of the manufacturing process;</p> <p>(c) The traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.</p>		
<p><b>EP 8.2 Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances</b></p> <p>(1) This clause applies in relation to a medical device that contains:</p> <p>(a) Tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable; and</p> <p>(b) Tissues, tissue derivatives, cells or substances of microbial or recombinant origin.</p> <p>(2) If the tissues, tissue derivatives, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the</p>	<p><b>GSPR13 Devices incorporating materials of biological origin</b></p> <p><b>GSPR 13.2</b> For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:</p> <p>(a) Where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;</p>	<p><b>GSPR 12 Devices incorporating materials of biological origin</b></p> <p>Where devices include tissues, cells and substances of animal, <b>human</b> or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person.</p> <p>In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.</p> <p>This might not apply to certain devices if the activity of the</p>	<p><b>Proposal 4(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>Extend the application of the "Note", in AUS EP 8.2(5), which currently only applies to "certain IVD medical devices", to also apply to "certain medical devices" (i.e., to apply to both IVD and non-IVD devices).</li> <li>Where devices utilise tissues or cells of animal origin or their derivatives, manufacturers are to include within their risk management system, a strategy to prevent transmission of animal-borne diseases, such as but not limited to spongiform encephalopathies.</li> </ul>



AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
<p>intended use of the tissues, tissue derivatives, cells or substances.</p> <p>(3) If the medical device contains tissues, tissue derivatives, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, tissue derivatives, cells or substances originated.</p> <p>(4) The processing, preservation, testing and handling of tissues, tissue derivatives, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person.</p> <p>(5) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.</p> <p><b>Note:</b> This may not apply to certain IVD medical devices if the characteristics mentioned in subclause 8.2(5) are integral to the intended purpose of the IVD medical device.</p>	<p>(b) Sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;</p> <p>(c) In the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.</p>	<p>microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.</p>	<p><i>The above requirement aligns with a similar requirement in the referenced Regulation (EU) No 722/2012:</i></p> <p><b>1.2 Process of risk assessment:</b></p> <p><i>“In order to ensure a high level of protection for patients and users, the manufacturer of devices utilising animal tissues or derivatives referred to in point 1.1 must implement an appropriate and well documented risk analysis and risk management strategy, to address all relevant aspects relating to TSE. He must identify the hazards and evaluate the risks associated with those tissues or derivatives, establish documentation on measures taken to minimise the risk of transmission and demonstrate the acceptability of the residual risk associated with the device utilising such tissues or derivatives, taking into account the intended use and the benefit of the device.”</i></p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>Expand the scope of EP 8.2 to include IVD devices incorporating tissues, cells and substances of <b>human origin</b>, or their derivatives, which are <b>non-viable or rendered non-viable</b>.</li> </ul> <p><i>The EU IVDR GSPR 12 is broader than the AUS EP 8.2, as it includes</i></p>

AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
			<p><i>IVD devices that contain biological substances of human origin.</i></p> <p><i>Our IVD devices framework <b>does</b> include devices which contain biological material of both animal <b>and human</b> origin that is non-viable or rendered non-viable, although this is <b>not currently captured</b> within our Essential Principles.</i></p> <p><i>Any device that includes biological material <b>that is viable</b> is regulated as a biological under our Biologicals Regulatory Framework.</i></p>
<p>No equivalent Essential Principle.</p>	<p><b>GSPR 13.3 Devices incorporating materials of biological origin</b></p> <p>For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.</p>	<p>No equivalent EU GSPR in IVDR.</p>	<p><b>Proposal 4(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• To include devices containing non-human and non-animal substances or their derivatives which are non-viable or rendered non-viable, not covered under EP 8.2(1)(a, b)</li> <li>• For non-human and non-animal substances that are non-viable or rendered non-viable, equivalent requirements to those already applied under AUS Essential Principle 8.2</li> </ul> <p><i>The EU MDR GSPR 13.3 is a catch-all clause to include anything other than substances from human or animal origin, which are non-viable</i></p>

AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
			<i>or rendered non-viable. As such, we are proposing to introduce a similar “catch-all” clause. This may result in changes to where recombinant and microbial origin material are included but will not change the requirements for compliance.</i>
No equivalent AUS Essential Principle.	<b>GSPR 11 Infection and microbial contamination</b> <b>GSPR 11.2</b> Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	No equivalent EU GSPR in IVDR.	<b>Proposal 4(a) NEW</b> <b>For non-IVD devices:</b> <ul style="list-style-type: none"> <li>Where necessary, devices are to be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.</li> </ul>
No equivalent AUS Essential Principle.	<b>GSPR 11.3</b> Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	<b>GSPR 11.2</b> Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.	<b>Proposal 4(a) NEW</b> <b>For all devices:</b> <ul style="list-style-type: none"> <li>Introduce <b>specific microbial state</b> and requirements that the device be designed, produced and packed in a way to ensure that the device maintains its specific microbial state when it is supplied, stored and transported in accordance with the directions of the manufacturer, until the protective packaging is opened or damaged.</li> </ul>
<b>EP 8.3 Medical devices to be supplied in a sterile state</b>	<b>GSPR 11.4</b> Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate		<b>Proposal 4(a) NEW</b> <b>For non-IVD devices:</b>

AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
<p>(1) This clause applies in relation to a medical device that is intended by the manufacturer to be supplied in a sterile state.</p> <p>(2) The device must be designed, produced and packed in a way that ensures that the device is sterile when it is supplied, and will remain sterile, if stored and transported in accordance with the directions of the manufacturer, until the protective packaging is opened or damaged.</p>	<p>procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use.</p> <p>It shall be ensured that the integrity of that packaging is clearly evident to the final user.</p>		<ul style="list-style-type: none"> <li>Non-IVD devices supplied <b>sterile</b> are to ensure that the integrity of the packaging is to be clearly evident to the final user.</li> </ul> <p><i>Only the last sentence of MDR GSPR 11.4 introduces a new requirement, the intent of the remaining requirement is already aligned.</i></p>
<p>(3) The device must be produced and sterilised using an appropriate validated method.</p>	<p><b>MDR GSPR 11.5 and IVDR GSPR 11.3</b></p> <p>Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.</p>		<p>No proposed changes.</p>
<p>(4) The device must be produced in appropriately controlled conditions.</p>	<p><b>MDR GSPR 11.6 and IVDR GSPR 11.4</b></p> <p>Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.</p>		<p><b>Proposal 4(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Manufacture of devices to be supplied is to occur in appropriate and controlled <b>facilities</b>.</li> </ul>
<p><b>EP 8.4 Medical devices to be supplied in a non-sterile state</b></p> <p>(1) A medical device that is intended by the manufacturer to be supplied in a non-sterile state must be packed in a way that ensures that the device maintains the level of</p>	<p><b>MDR GSPR 11.7 and IVDR GSPR 11.5</b></p> <p>Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination;</p> <p>The packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.</p>		<p>No proposed change.</p>

AUS Essential Principle 8	EU MDR	EU IVDR	Proposal 4 - Intent and <i>comments</i>
<p>cleanliness stipulated by the manufacturer.</p> <p>(2) If the device is intended to be sterilised before it is used, the device must be packed in a way that:</p> <p>(a) Ensures that the risk of microbial contamination is minimised; and</p> <p>(b) Is suitable, having regard to the method of sterilisation that the manufacturer indicates is to be used for the device.</p> <p>(3) The device must be produced in appropriately controlled conditions.</p>			
<p><b>EP 8.5 Distinction between medical devices supplied in sterile and non-sterile state</b></p> <p>If a medical device is supplied in both a sterile state and a non-sterile state, the information provided with the device must clearly indicate whether the device is in a sterile state or a non-sterile state.</p>	<p><b>MDR GSPR 11.8 and IVDR GSPR 11.6</b></p> <p>The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.</p>		<p><b>Proposal 4(a) <span style="color: red;">NEW</span></b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Extend the requirements for labelling of identical or similar devices, supplied both sterile and non-sterile, to be easily distinguished, in addition to the marking used to indicate the device is sterile.</li> </ul>

## Proposal 5: AUS Essential Principle 9 - Construction and environmental properties

AUS Essential Principle 9	EU MD Regulations	EU IVD Regulations	Proposal 5 - Intent and <i>comments</i>
<p><b>EP 9 Construction and environmental properties</b></p> <p><b>EP 9.1 Medical devices intended to be used in combination with other devices or equipment</b></p> <p>A medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment (including a connection system) must be designed and produced in a way that ensures that:</p> <ul style="list-style-type: none"> <li>(a) The medical device, and any other device or equipment with which it is used, operate in a safe way; and</li> <li>(b) The intended performance of the device, and any other device or equipment with which it is used, is not impaired</li> </ul>	<p><b>GSPR 14. Construction of devices and interaction with their environment</b></p> <p><b>GSPR 14.1</b> If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.</p>	<p><b>GSPR 13. Construction of devices and interaction with their environment</b></p> <p><b>GSPR 13.1</b> If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use</p>	<p><b>Proposal 5(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that information on the label, or in the instructions for use, includes: <ul style="list-style-type: none"> <li>– any restrictions on combinations with other devices or equipment</li> <li>– minimising risks of connections handled by the user, such as misconnection.</li> </ul> </li> </ul> <p><i>Clauses related to information to be provided with the device, may be included under AUS Essential Principle 13, depending on legislative structure.</i></p>
<p><b>EP 9.2 Minimisation of risks associated with use of medical devices</b></p> <p>A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:</p> <ul style="list-style-type: none"> <li>(a) The risk of injury arising from the physical features of the device;</li> </ul>	<p><b>MDR GSPR 14.2 and/IVDR GSPR 13.2</b> Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:</p> <ul style="list-style-type: none"> <li>(a) The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;</li> <li>(b) Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures,</li> </ul>		<p><b>Proposal 5(a) <b>NEW</b></b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify expectations through including equivalent examples in MDR/IVDR clauses (a)(b).</li> <li>• Clarify the expectation identified in MDR/IVDR (c), to remove or minimise risks associated with use</li> </ul>

AUS Essential Principle 9	EU MD Regulations	EU IVD Regulations	Proposal 5 - Intent and <i>comments</i>
(b) Any risks associated with reasonably foreseeable environmental conditions;	<p>pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;</p> <p>(c) The risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;</p> <p>(d) The risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;</p> <p>(e) The risks of accidental ingress of substances into the device;</p>		<p>of the device when it comes into contact with various materials, liquids and substances, when used as intended.</p> <ul style="list-style-type: none"> <li>Clarify the expectation identified in MDR/IVDR (d), to remove or minimise risks associated with negative interactions between software and the IT environment the device operates within and interacts.</li> </ul>
<p><b>EP 9.2 continued...</b></p> <p>(c) The risk of reciprocal interference involving other devices that are normally used in an investigation or treatment of the kind for which the device is intended to be used;</p>	<p><b>GSPR 14.2 continued...</b></p> <p>(f) The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;</p>	<p><b>GSPR 13.2 continued...</b></p> <p>(f) The risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended;</p> <p>(g) The risks of any foreseeable interference with other devices.</p>	<p>For IVD devices: <b>NEW</b></p> <ul style="list-style-type: none"> <li>Remove or minimise risks associated with incorrect identification of specimens and erroneous results, including examples for clarity.</li> </ul> <p><i>This requirement may be included under AUS Essential Principle 15 (IVDs only), depending on legislative structure.</i></p>
<p><b>EP 9.2 continued...</b></p>	<p><b>GSPR 14.2 continued....</b></p> <p>(g) Risks arising where maintenance or calibration are not possible (as with</p>	<p><b>No equivalent EU GSPR in IVDR.</b></p>	<p>No proposed changes.</p>

AUS Essential Principle 9	EU MD Regulations	EU IVD Regulations	Proposal 5 - Intent and <i>comments</i>
<p>(d) Any risks arising if maintenance or calibration of the device is not possible;</p> <p>(e) Any risks associated with the ageing of materials used in the device;</p> <p>(f) Any risks associated with loss of accuracy of any measuring or control mechanism of the device;</p>	<p>implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.</p>		
<p><b>EP 9.2 continued...</b></p> <p>(g) The risk of fire or explosion occurring during normal use of the device, and in the event of a single fault condition, especially if the device is intended to be exposed to flammable substances or substances that can cause combustion;</p>	<p><b>MDR GSPR 14.3 and IVDR GSPR 13.3</b></p> <p>Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.</p>		<p><b>Proposal 5(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include reference to devices intended to be used with explosive substances.</li> </ul>
<p><b>EP 9.2 continued...</b></p> <p>(h) The risks associated with disposal of any waste substances.</p>	<p><b>GSPR 14.7</b> Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person.</p> <p>To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use</p>	<p><b>GSPR 13.6</b> Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person.</p> <p>To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such</p>	<p><b>Proposal 5(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Identify and test procedures to enable safe disposal of devices after use and any waste products.</li> <li>• Identified and tested disposal procedures for the device, and any related waste products, are to be</li> </ul>



AUS Essential Principle 9	EU MD Regulations	EU IVD Regulations	Proposal 5 - Intent and <i>comments</i>
		procedures shall be described in the instructions for use.	documented in the instructions for use.*  <i>*This requirement may be included under AUS Essential Principle 13 (information provided with the device).</i>
No equivalent AUS Essential Principle.	<b>MDR GSPR 14.4 and IVDR GSPR 13.4</b> Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		<b>Proposal 5(a) NEW</b> <b>For all devices:</b> <ul style="list-style-type: none"><li>Require devices to be designed and manufactured to ensure adjustment, calibration, and maintenance can be done safely and effectively.</li></ul>
No equivalent AUS Essential Principle.	<b>MDR GSPR 14.5 and IVDR GSPR 13.5</b> Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.		<b>Proposal 5(a) NEW</b> <b>For all devices:</b> <ul style="list-style-type: none"><li>Require devices intended to operate together with other devices or products to be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.</li></ul>
No equivalent AUS Essential Principle (that applies to <b>all devices</b> ).	<b>GSPR 14.6</b> Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose,	<b>GSPR 13.7</b> The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in	<b>Proposal 5(a) NEW</b> <b>For all devices:</b> <ul style="list-style-type: none"><li>Require any measurement, monitoring or display scale to be</li></ul>

AUS Essential Principle 9	EU MD Regulations	EU IVD Regulations	Proposal 5 - Intent and <i>comments</i>
	users and the environmental conditions in which the devices are intended to be used.	line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	<p>designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.</p> <p><i>EP 10(2) for medical devices with a measuring function is equivalent, however this MDR and IVDR GSPR applies to <b>all devices</b>, not only “those with a measuring function”.</i></p>

## No changes: AUS Essential Principle 10 – Medical devices with a measuring function

We consider AUS Essential Principle 10 to be aligned in intent with the equivalent European GSPRs. No changes are proposed.

AUS Essential Principle 10	EU MD Regulations	EU IVD Regulations
<p><b>EP 10 Medical devices with a measuring function</b></p> <p>(1) A medical device that has a measuring function must be designed and produced in a way that ensures that the device provides accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device.</p>	<p><b>GSPR 15 Devices with a diagnostic or measuring function</b></p> <p><b>GSPR 15.1</b> Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.</p>	<p><b>GSPR 14 Devices with a measuring function</b></p> <p><b>GSPR 14.1.</b> Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.</p>
<p>(2) The measurement, monitoring and display scale of the device must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device.</p>	<p><b>MDR GSPR 14.6</b> has equivalent intent to this requirement, except it applies to <b>all devices</b>, not just “medical devices with a measuring function”.</p> <p><b>MDR GSPR 14.6</b> is included under EP 9.</p>	<p><b>IVDR GSPR 1.7</b> has equivalent intent to this requirement, except it applies to <b>all IVD devices</b>, not just “medical devices with a measuring function”.</p> <p><b>IVDR GSPR 13.7</b> is included under EP 9</p>

AUS Essential Principle 10	EU MD Regulations	EU IVD Regulations
<p>(3) The measurements made by the device must be expressed:</p> <p>(a) In Australian legal units of measurement or be compared to at least one point of reference indicated in Australian legal units of measurement; or</p> <p>(b) If the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed under the National Measurement Act 1960, in units approved by the Secretary for the particular device.</p>	<p><b>MDR GSPR 15.2 and IVDR GSPR 14.2</b></p> <p>The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).</p>	

## Proposal 6: AUS Essential Principle 11 – Protection against radiation

AUS Essential Principle 11	EU MD Regulations	EU IVD Regulations	Proposal 6 - Intent and <i>comments</i>
<p><b>EP 11 Protection against radiation</b> <b>EP 11.1 Minimisation of exposure to radiation</b></p> <p>A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to radiation is minimised, having regard to the levels of radiation required to enable the device to perform its therapeutic and diagnostic functions and the intended purpose of the device.</p>	<p><b>GSPR 16 Protection against radiation</b> <b>GSPR 16.1 General</b></p> <p>(a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.</p>	<p><b>GSPR 15 Protection against radiation</b> <b>GSPR 15.1</b> Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.</p>	<p><b>Proposal 6(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Clarify that reducing exposure to radiation includes intended, unintended, stray or scattered radiation.</li> </ul> <p><i>The remaining requirements of EP 11.1 are considered equivalent to the intent of the EU clauses.</i></p>

AUS Essential Principle 11	EU MD Regulations	EU IVD Regulations	Proposal 6 - Intent and <i>comments</i>
<p><b>EP 11.2 Medical devices intended to emit radiation</b></p> <p>(1) This clause applies in relation to a medical device that is intended by a manufacturer to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission.</p> <p>(2) The device must be designed and produced in a way that ensures that the user can control the level of the emission.</p> <p>(3) The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters.</p> <p>(4) If practicable, the device must be fitted with a visual indicator or an audible warning, or both, that operates if potentially hazardous levels of radiation are emitted.</p>	<p><b>GSPR 16.2 Intended radiation</b></p> <p>(a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions.</p> <p>(b) Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.</p> <p>(c) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.</p>	<p><b>GSPR 15.2</b> When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be:</p> <p>(a) Designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and</p> <p>(b) Fitted with visual displays and/or audible warnings of such emissions.</p>	<p><b>Proposal 6(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>Clarify that the visual indicator and/or audible warning referred to in Clause (4) are to apply, if practicable, when the device <b>is in operation</b> and emitting radiation</li> <li>Clarify the intent of EP 11.2(3) is equivalent to MDR GSPR 16.2(a), that devices are to provide reproducibility of relevant variable parameters within an acceptable tolerance.</li> </ul> <p><i>The existing EP 11.2(3) was unclear, and we are proposing to re-worded for clarity. No additional requirements.</i></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Amend the wording “visible radiation” and “invisible” radiation to “ionising radiation” and “non-ionising” radiation.</li> </ul> <p><i>The proposed amended terminology will provide consistency with other National Regulations on radiation safety and the EU Regulations.</i></p>
<p><b>EP 11.3 Minimisation of exposure to unintended radiation</b></p>	<p><b>GSPR 16.3</b> Devices shall be designed and manufactured in such a way that exposure of patients, users and other</p>	<p><b>No equivalent EU GSPR in IVDR.</b></p>	<p>No proposed change.</p>

AUS Essential Principle 11	EU MD Regulations	EU IVD Regulations	Proposal 6 - Intent and <i>comments</i>
<p>A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to the emission of unintended, stray or scattered radiation is minimised.</p>	<p>persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.</p>		
<p><b>EP 11.4 Operating instructions</b></p> <p>The operating instructions for a medical device that emits radiation must include detailed information about the following matters:</p> <ul style="list-style-type: none"> <li>(a) The nature of the radiation emitted;</li> <li>(b) The means by which patients and users can be protected from the radiation;</li> <li>(c) Ways to avoid misusing the device;</li> <li>(d) Ways to eliminate any risks inherent in the installation of the device.</li> </ul>	<p><b>GSPR 16.1 General</b></p> <p>(b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate.</p> <p>Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.</p>	<p><b>GSPR 15.3</b> The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate.</p> <p>Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.</p>	<p><b>Proposal 6(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• To require information in the instructions for use on acceptance and performance testing, acceptance criteria and maintenance procedures.</li> </ul> <p><i>This may also, or alternatively, be included under Essential Principle 13, depending on legislative structure.</i></p>
<p><b>EP 11.5 Medical devices intended to emit ionising radiation – additional requirements</b></p> <p>(1) This clause applies, in addition to clauses 11.1 to 11.4, in relation to a medical device that is intended</p>	<p><b>GSPR 16.4. Ionising radiation</b></p> <p>(a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers</p>	<p>No equivalent EU GSPR in IVDR.</p>	<p>No proposed change.</p>

AUS Essential Principle 11	EU MD Regulations	EU IVD Regulations	Proposal 6 - Intent and <i>comments</i>
by the manufacturer to emit ionising radiation.	arising from exposure to ionising radiation.		
(2) The device must be designed and produced in a way that ensures that, if practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be controlled and varied, having regard to the intended purpose of the device.	(b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, <b>if possible, monitored during treatment.</b>		<p><b>Proposal 6(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• require radiation to be monitored during treatment, where possible.</li> </ul>
(3) If the device is intended to be used for diagnostic radiology, the device must be designed and produced in a way that ensures that, when used in relation to a patient for a purpose intended by the manufacturer:	(c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.		<p><b>Proposal 6(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that part (b) applies to both patients <b>and</b> users (changed from “patients <b>or</b> users”).</li> </ul>
(4) If the device is intended to be used for therapeutic radiology, the device must be designed and produced in a way that ensures	(d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in		No proposed change.

AUS Essential Principle 11	EU MD Regulations	EU IVD Regulations	Proposal 6 - Intent and <i>comments</i>
that the delivered dose of radiation, the type and energy of the radiation beam, and, if appropriate, the energy distribution of the radiation beam, can be reliably controlled and monitored.	such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.		
<p><i>The following proposals relate to the application of existing AUS Essential Principles to devices that emit radiation. None of the following principles are included as separate requirements within the EU Regulations for radiation safety, however, we are proposing to provide additional clarity to manufacturer's that other AUS Essential Principles are critical to apply for these types of devices.</i></p> <p><b>Proposal 6(b) AUS-specific</b></p> <p>Our intent is to increase clarity for manufacturers on the regulatory expectations that apply to devices that emit radiation:</p> <p>For all devices:</p> <ul style="list-style-type: none"> <li>• Clarity that any waste products are disposed of appropriately, as required under proposals for AUS Essential Principle 9.</li> <li>• Reiterate the requirements of AUS Essential Principle 7.5, for manufacturers to minimise risks associated with leaching, such as unintended radiation when in operation and any leakage of radiation when not in operation.</li> <li>• Reiterate the requirements of AUS Essential Principle 13.4(3) Item 22, that manufacturers must inform users and patients of any warnings, precautions, contraindications and <b>measures to be taken</b> in the event of a <b>malfunction</b> of the device or <b>changes in its performance</b> that may affect safety.</li> </ul> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Reiterate the requirements of AUS Essential Principle 12.12, <i>Protection against risks associated with administration of energy or substances</i>, must be applied to devices that emit radiation.</li> </ul>			

## Proposal 7: AUS Essential Principle 12 – Medical devices connected to or equipped with an energy source

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p><b>EP 12.1 Programmed or programmable medical device or software that is a medical device</b></p> <p>(1) A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that:</p> <p>(a) The safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and</p> <p>(b) Any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and</p> <p>(c) The device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and</p>	<p><b>MDR GSPR 17 and IVDR GSPR 16. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves</b></p> <p><b>MDR GSPR 17.1 and IVDR GSPR 16.1</b></p> <p>Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use.</p> <p>In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.</p>		<p>No proposed changes.</p>



AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>(d) If relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner:</p> <p>(i) Following the disruption to services upon which the device is dependent for the device's operation; and</p> <p>(ii) Following the performance of the device being adversely affected; and</p> <p>(e) If relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and</p> <p>(f) If relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and</p> <p>(g) If relevant, the privacy of the data or information is maintained.</p>			
<p><b>EP 12.1 continued.....</b></p> <p>(2) A programmed or programmable medical device, or software that is a medical device, must be developed,</p>	<p><b>MDR GSPR 17.2 and IVDR GSPR 16.2</b></p> <p>For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of</p>		<p>No proposed changes.</p>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution).</p>	<p>development life cycle, risk management, including information security, verification and validation.</p>		
<p><b>EP 12.1 continued.....</b></p> <p>(3) A programmed or programmable medical device, or software that is a medical device, that is intended to be used in combination with computing platforms must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms.</p>	<p><b>MDR GSPR 17.3 and IVDR GSPR 16.3</b></p> <p>Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g., Size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).</p>		<p>No proposed changes.</p>
<p><b>EP 12.1 continued...</b></p> <p>(4) The manufacturer of a programmed or programmable medical device, or software that is a medical device, must provide instructions or information with the device that sets out requirements (including requirements about hardware,</p>	<p><b>MDR GSPR 17.4 and IVDR GSPR 16.4</b></p> <p>Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.</p>		<p>No proposed changes.</p>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>software, information technology environments and security measures) necessary to operate the device as intended.</p> <p>(5) A programmed or programmable medical device, or software that is a medical device, must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device, including where appropriate the following:</p> <ul style="list-style-type: none"> <li>(a) Protection against unauthorised access, unauthorised influence or unauthorised manipulation;</li> <li>(b) Minimisation of risks associated with known cybersecurity vulnerabilities (including either or both of remediation of known vulnerabilities and application of compensating controls);</li> <li>(c) Facilitation of the application of updates, patches, compensating controls and other improvements;</li> <li>(d) Disclosure of known vulnerabilities in the device or its components and associated mitigations;</li> <li>(e) Making available sufficient information for a user to make</li> </ul>	<p><b>MDR GSPR 18.8</b> Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.</p>		

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls. And other improvements</p>			
<p><b>EP 12.1 continued.....</b></p> <p>(6) The manufacturer of a programmed or programmable medical device, or software that is a medical device, having regard to the intended purpose of the device, the generally acknowledged state of the art and best practice, must ensure that the data that influences the performance of the device is:</p> <p>(a) Representative; and</p> <p>(b) Of sufficient quality; and</p> <p>(c) Maintained to ensure integrity; and</p> <p>(d) Managed to reduce bias.</p>	<p><b>No equivalent EU GSPR in IMDR or VDR.</b></p>		<p>No proposed changes.</p>
<p><b>No equivalent AUS Essential Principle.</b></p>	<p><b>GSPR 18 Active devices and devices connected to them.</b></p> <p><b>MDR GSPR 18.1</b> For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks</p>	<p><b>GSPR 17 Devices connected to or equipped with an energy source.</b></p> <p><b>IVDR GSPR 17.1</b> For non-implantable active devices, in the event of a single fault condition, appropriate means shall be</p>	<p><b>Proposal 7(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Clarify that non-implantable active devices (MDR) and devices connected to or equipped with a power supply (IVDR) are to</li> </ul>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and <i>comments</i>
		adopted to eliminate or reduce as far as possible consequent risks	minimise risks in the event of a single fault condition.
<p><b>EP 12.2 Safety dependent on internal power supply</b></p> <p>(1) This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an internal power supply for the device.</p> <p>(2) The device must be fitted with a means of determining the state of the power supply.</p>	<p><b>MDR GSPR 18.2 and IVDR GSPR 17.2</b> Devices where the safety of the patient depends on an internal power supply shall be equipped with:</p> <ul style="list-style-type: none"> <li>– a means of determining the state of the power supply and</li> <li>– an appropriate warning or indication for when the capacity of the power supply becomes critical.</li> </ul> <p>If necessary, such warning or indication shall be given prior to the power supply becoming critical.</p>		<p><b>Proposal 7(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Require an appropriate warning or indication for when the capacity of the power supply becomes critical.</li> <li>• If necessary, such warning or indication shall be given <b>prior</b> to the power supply becoming critical.</li> </ul>
<p><b>EP 12.3 Safety dependent on external power supply</b></p> <p>(1) This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an external power supply for the device.</p> <p>(2) The device must be fitted with an alarm system that indicates whether a power failure has occurred.</p>	<p><b>GSPR 18.3</b> Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure</p>	No equivalent EU GSPR in IVDR.	No proposed changes.
<p><b>EP 12.4 Medical devices intended to monitor clinical parameters</b></p> <p>A medical device that is intended by the manufacturer to be used to monitor one</p>	<p><b>GSPR 18.4</b> Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm</p>	No equivalent EU GSPR in IVDR.	No proposed changes.

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<p>or more clinical parameters of a patient must be fitted with an appropriate alarm system to warn the user if a situation has developed that could lead to the death of the patient or a severe deterioration in the state of the patient's health</p>	<p>systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.</p>		
<p><b>EP 12.5 Minimisation of risk of electromagnetic fields</b> A medical device must be designed and produced in a way that ensures that the risk of an electromagnetic field being created that could impair the operation of other devices or equipment being used in the vicinity of the medical device is minimised.</p>	<p><b>MDR GSPR 18.5 and IVDR GSPR 17.3</b> Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.</p>		<p><b>Proposal 7(a) NEW</b> <b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Require devices to be designed and manufactured to minimise risks of creating an electromagnetic field/interference that could impair not only other equipment, but also the device itself.</li> </ul>
<p><b>No equivalent AUS Essential Principle.</b></p>	<p><b>MDR GSPR 18.6 and IVDR GSPR 17.4</b> Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.</p>		<p><b>Proposal 7(a) NEW</b> <b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Require devices to be designed and manufactured to provide a level of intrinsic immunity to electromagnetic interference.</li> </ul>
<p><b>EP 12.6 Protection against electrical risks</b> A medical device must be designed and produced in a way that ensures that, as far as possible, when the device is</p>	<p><b>GSPR 18.7</b> Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in</p>	<p><b>GSPR 17.5.</b> Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal</p>	<p>No proposed changes.</p>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>installed correctly, and the device is being used for an intended purpose under normal conditions of use and in the event of a single fault condition, patients, users, and any other persons, are protected against the risk of accidental electric shock.</p>	<p>the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.</p>	<p>use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.</p>	
<p><b>EP 12.7 Protection against mechanical risks</b></p> <p>A medical device must be designed and produced in a way that ensures that a patient, the user, and any other person, is protected against any mechanical risks associated with the use of the device.</p>	<p><b>GSPR 20 Protection against mechanical and thermal risks</b></p> <p><b>GSPR 20.1</b> Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts</p>	<p><b>GSPR 18 Protection against mechanical and thermal risks</b></p> <p><b>GSPR 18.1</b> Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.</p> <p><b>GSPR 18.2</b> Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.</p>	<p><b>Proposal 7(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Increase clarity through examples such as, but not limited to, resistance to movement, instability and moving parts.</li> </ul> <p><b>For IVD device: NEW</b></p> <ul style="list-style-type: none"> <li>• Require devices to be sufficiently stable under the foreseen operating conditions, including being suitable to: <ul style="list-style-type: none"> <li>– withstand stresses inherent to the foreseen working environment</li> <li>– retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.</li> </ul> </li> </ul>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>No equivalent AUS Essential Principle.</p>	<p>No equivalent EU GSPR in MDR.</p>	<p><b>GSPR 18.3</b> Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.</p> <p>Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.</p>	<p><b>Proposal 7(a) NEW</b></p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Require devices to include appropriate protections from any risks due to: <ul style="list-style-type: none"> <li>– moving parts</li> <li>– break-up or detachment</li> <li>– leakage of substances</li> </ul> </li> <li>• Require devices that incorporate any guards or other means of protection, in particular against moving parts, to be secure and not interfere with access for the normal operation of the device or restrict routine maintenance of the device as intended by the manufacturer.</li> </ul>
<p><b>EP 12.8 Protection against risks associated with vibration</b></p> <p>(1) A medical device must be designed and produced in a way that ensures that any risks associated with vibrations generated by the device are minimised.</p> <p>(2) If vibrations are not part of the intended performance of the device, particular attention must be given to</p>	<p><b>MDR GSPR 20.2 and IVDR GSPR 18.4</b></p> <p>Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.</p>	<p>No proposed changes.</p>	



AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
relevant technical progress, and the available means, for limiting vibrations, particularly at source			
<p><b>EP 12.9 Protection against risks associated with noise</b></p> <p>(1) A medical device must be designed and produced in a way that ensures that any risks associated with noise emitted by the device are minimised.</p> <p>(2) If noise is not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for reducing the emission of noise, particularly at source.</p>	<p><b>MDR GSPR 20.3 and IVDR GSPR 18.5</b></p> <p>Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.</p>		No proposed changes.
<p><b>EP 12.10 Protection against risks associated with terminals and connectors</b></p> <p>A medical device that is intended by the manufacturer to be connected to an electric, gas, hydraulic, pneumatic or other energy supply must be designed and produced in a way that ensures that any risks to the user associated with the handling of a terminal or connector on the device, in relation to the energy supply, are minimised.</p>	<p><b>MDR GSPR 20.4 and IVDR GSPR 18.6</b></p> <p>Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.</p>		No proposed changes.
No equivalent AUS Essential Principle.	<p><b>MDR GSPR 20.5 and IVDR GSPR 18.7</b></p> <p>Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of</p>		Proposal 7(a) <b>NEW</b>

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	<p>such parts or, failing this, by information given on the parts themselves and/or their housings.</p> <p>The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.</p>		<p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Require errors when fitting and refitting parts, which could be a source of risk, to be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.</li> <li>Require the same information to be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.</li> </ul>
<p><b>EP 12.11 Protection against risk associated with heat</b></p> <p>A medical device must be designed and produced in a way that ensures that during normal use, any accessible part of the device (other than any part intended by the manufacturer to supply heat or reach a given temperature) and any area surrounding an accessible part of the device, does not reach a potentially dangerous temperature.</p>	<p><b>MDR GSPR 20.6 and IVDR GSPR 18.8</b> Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.</p>		<p>No proposed changes.</p>
<p><b>EP 12.12 Protection against risks associated with administration of energy or substances</b></p> <p>(1) This clause applies in relation to a medical device that is intended by</p>	<p><b>MDR GSPR 21 Protection against the risks posed to the patient or user by devices supplying energy or substances</b></p>	<p>No equivalent EU GSPR in IVDR.</p>	<p>No proposed changes.</p>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
<p>the manufacturer to be used to administer energy or a substance to a patient.</p> <p>(2) The device must be designed and produced in a way that ensures that:</p> <p>(a) The delivered rate and amount of energy, or of the substance, can be set and maintained accurately to ensure the safety of the patient and the user; and</p> <p>(b) As far as possible, the accidental release of dangerous levels of energy or of the substance is prevented.</p> <p>(3) The device must be fitted with a means of indicating or, if appropriate, preventing inadequacies in the rate and amount of energy, or of the substance, administered that might cause danger to the patient, the user or any other person.</p>	<p><b>GSPR 21.1</b> Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.</p> <p><b>GSPR 21.2</b> Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.</p>		
<p>(4) The functions of each control and indicator on the device must be clearly specified on the device.</p> <p>(5) If the instructions for the operation of the device, or the operating or adjustment parameters for the device, are displayed by means of a visual system incorporated into the</p>	<p><b>GSPR 21.3</b> The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.</p>	<p>No equivalent EU GSPR in IVDR.</p>	<p>No proposed changes.</p>

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device, the instructions or parameters must be able to be understood by the user and, if appropriate, the patient.			
<p><b>No equivalent AUS Essential Principle.</b> Related to EP 12.13 for active implantable devices.</p>	<p><b>GSPR 19 Particular requirements for active implantable devices</b></p> <p><b>GSPR 19.1</b> Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:</p> <p>(a) Risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,</p> <p>(b) Risks connected with medical treatment, in particular those resulting from the use of defibrillators or high- frequency surgical equipment, and</p> <p>(c) Risks which may arise where maintenance and calibration are impossible, including:</p> <ul style="list-style-type: none"> <li>– excessive increase of leakage currents,</li> <li>– ageing of the materials used,</li> </ul>	<p><b>No equivalent EU GSPR in IVDR.</b></p>	<p><b>Proposal 7(a) NEW</b></p> <p><b>For active implantable devices:</b></p> <ul style="list-style-type: none"> <li>• Require active implantable devices to be designed and manufactured in such a way as to remove or minimize as far as possible: <ul style="list-style-type: none"> <li>– risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,</li> <li>– risks connected with medical treatment, in particular those resulting from the use of defibrillators or high- frequency surgical equipment, and</li> <li>– risks which may arise where maintenance and calibration are impossible, including: <ul style="list-style-type: none"> <li>▪ excessive increase of leakage currents</li> </ul> </li> </ul> </li> </ul>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and comments
	<ul style="list-style-type: none"> <li>– excess heat generated by the device,</li> <li>– decreased accuracy of any measuring or control mechanism.</li> </ul>		<ul style="list-style-type: none"> <li>▪ ageing of the materials used</li> <li>▪ excess heat generated by the device</li> <li>▪ decreased accuracy of any measuring or control mechanism.</li> </ul>
<p>No equivalent AUS Essential Principle. Related to EP 12.13.</p>	<p><b>GSPR 19.2</b> Active implantable devices shall be designed and manufactured in such a way as to ensure:</p> <ul style="list-style-type: none"> <li>– If applicable, the compatibility of the devices with the substances they are intended to administer, and</li> <li>– the reliability of the source of energy.</li> </ul>	<p>No equivalent EU GSPR in IVDR.</p>	<p><b>Proposal 7(a) NEW</b></p> <p><b>For active implantable devices:</b></p> <ul style="list-style-type: none"> <li>• Require active implantable devices to be designed and manufactured in such a way as to ensure: <ul style="list-style-type: none"> <li>– if applicable, the compatibility of the devices with the substances they are intended to administer, and</li> <li>– the reliability of the source of energy.</li> </ul> </li> </ul>
<p>No equivalent AUS Essential Principle. Related to EP 12.13.</p>	<p><b>GSPR 19.3</b> Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.</p>	<p>No equivalent EU GSPR in IVDR.</p>	<p><b>Proposal 7(a) NEW</b></p> <p><b>For active implantable devices:</b></p> <ul style="list-style-type: none"> <li>• Require active implantable devices and, if appropriate, their component parts to be identifiable to allow any necessary measure</li> </ul>

AUS Essential Principle 12	EU MD Regulations	EU IVD Regulations	Proposal 7 - Intent and <i>comments</i>
			to be taken following the discovery of a potential risk in connection with the devices or their component parts.
<p><b>EP 12.13 Active implantable medical devices</b></p> <p>(1) An active implantable medical device must incorporate, display, emit or exhibit a code or unique characteristic that can be used to identify:</p> <p>(a) the type of device; and</p> <p>(b) the manufacturer of the device; and</p> <p>(c) the year of manufacture of the device.</p> <p>(2) The code or unique characteristic must be able to be read without the need for surgery to the person in whom the device is implanted.</p>	<p><b>GSPR 19.4</b> Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.</p>	<p>No equivalent EU GSPR in IVDR.</p>	<p>No proposed changes.</p>

### Proposal 8: AUS Essential Principle 15 – Principles applying to IVD medical devices only

AUS Essential Principle 15 - IVDs	EU IVD Regulations only	Proposal 8 - Intent and <i>comments</i>
<p><b>EP 15 Principles applying to IVD medical devices only</b></p>	<p><b>GSPR 9. Performance characteristics</b></p> <p><b>GSPR 9.1</b> Devices shall be designed and manufactured in such a way that they are suitable for</p>	<p>Proposal 8(a)</p> <ul style="list-style-type: none"> <li>Expand the clarity provided, that analytical performance, includes</li> </ul>

AUS Essential Principle 15 - IVDs	EU IVD Regulations only	Proposal 8 - Intent and <i>comments</i>
<p>(1) An IVD medical device must be designed and manufactured in a way in which the analytical and clinical characteristics support the intended use, based on appropriate scientific and technical methods.</p> <p>(2) An IVD medical device must be designed in a way that addresses accuracy, precision, sensitivity, specificity, stability, control of known relevant interference and measurement of uncertainty, as appropriate</p>	<p>the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:</p> <p>(a) The analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross reactions; and</p> <p>(b) The clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.</p>	<p>trueness, precision, accuracy, limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross reactions.</p> <ul style="list-style-type: none"> <li>• Include clarify that clinical performance, specifically refers to diagnostic sensitivity, diagnostic specificity as well additionally includes positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.</li> </ul>
<p><i>Refer to AUS Essential Principle 4.</i></p>	<p><b>GSPR 9 continued....</b></p> <p><b>GSPR 9.2</b> The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.</p>	<p><b>Proposal 8(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Clarify that performance characteristics of the device shall be maintained during the lifetime of the device, as indicated by the manufacturer.</li> </ul> <p><i>While AUS EP 4 covers long-term safety of devices, this principle will be included again under AUS EP 15.</i></p>

AUS Essential Principle 15 - IVDs	EU IVD Regulations only	Proposal 8 - Intent and <i>comments</i>
<p><b>EP 15 continued....</b></p> <p>(3) If performance of an IVD medical device depends in whole or part on the use of calibrators or control materials, the traceability of values assigned to the calibrators or control material must be assured through a quality management system.</p>	<p><b>GSPR 9 continued....</b></p> <p><b>GSR 9.3</b> Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.</p>	<p><b>Proposal 8(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Require metrological traceability of values assigned to calibrators and/or control materials to be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order.</li> <li>• Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.</li> </ul>
<p><b>No equivalent AUS Essential Principle.</b></p>	<p><b>GSPR 9 continued....</b></p> <p><b>GSPR 9.4</b> The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions:</p> <p>(a) For devices for self-testing, performances obtained by lay persons;</p> <p>(b) For devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).</p>	<p><b>Proposal 8(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Require the characteristics and performances of the device to be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions: <ul style="list-style-type: none"> <li>– for devices for self-testing, performances obtained by lay persons;</li> <li>– for devices for point of care testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).</li> </ul> </li> </ul>



AUS Essential Principle 15 - IVDs	EU IVD Regulations only	Proposal 8 - Intent and <i>comments</i>
<i>Aligned under other Essential Principles.</i>	<b>IVDR GSPR 10-18</b>	<p><i>IVDR GSPRs 10-18 are aligned with existing Essential Principles, outside of EP 15:</i></p> <p><i>GSPR 10 – refer to EP 7 (Proposal 3)</i></p> <p><i>GSPR 11-12 – refer to EP 8 (Proposal 4)</i></p> <p><i>GSPR 13 – refer to EP 9 (Proposal 5)</i></p> <p><i>GSPR 14 – refer to EP 10 (No changes)</i></p> <p><i>GSPR 15 – refer to EP 11 (Proposal 6)</i></p> <p><i>GSPR 16 - 18 – Refer to EP 12 (Proposal 7)</i></p>
<p><b>EP 15 continued....</b></p> <p>(4) An IVD medical device must, to the extent reasonably practicable, include provision for the user to verify, at the time of use, that the device will perform as intended by the manufacturer.</p>	<p><b>GSPR 19 Protection against the risks posed by devices intended for self-testing or near-patient testing</b></p> <p><b>GSPR 19.3</b> Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user:</p> <p>(a) Can verify that, at the time of use, the device will perform as intended by the manufacturer; and</p> <p>(b) Be warned if the device has failed to provide a valid result.</p>	<p><b>Proposal 8(b) - AUS-Specific</b></p> <ul style="list-style-type: none"> <li>All IVDs are to include a procedure by which the intended user is warned if the device fails to provide a valid result.</li> </ul> <p><i>IVDR GSPR 19 only applies to devices intended for self-testing or near patient testing. The equivalent AUS EP 15(4), however, applies to all IVDs. As such, we propose to apply the additional requirement of IVDR GSPR 19.3(b) to all IVDs. This simply reflects the expectation of compliance with the AUS General Essential Principles of Part 1.</i></p>
<p><b>EP 15 continued....</b></p> <p>(5) An IVD medical device for self-testing must be designed and manufactured so that it performs appropriately for its intended purpose, taking into account the skills and the means available to users</p>	<p><b>GSPR 19 continued.....</b></p> <p><b>GSPR 19.1</b> Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and</p>	<p><b>Proposal 8(a)</b></p> <ul style="list-style-type: none"> <li>Expand the scope of both EP 15 (5) and (6) to include devices for <b>point of care testing</b>.</li> </ul>

AUS Essential Principle 15 - IVDs	EU IVD Regulations only	Proposal 8 - Intent and <i>comments</i>
<p>and the influence resulting from variation that can reasonably be anticipated in the user's technique and environment.</p> <p>(6) The information and instructions provided by the manufacturer of an IVD medical device for self-testing must be easy for the user to understand and apply.</p>	<p>the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment.</p> <p>The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information.</p> <p>In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.</p>	<ul style="list-style-type: none"> <li>• Clarify the expectation that characteristics and performance of the device are to be evaluated by the manufacturer to ensure the device performs as intended, taking into account the intended user and intended use environment.</li> <li>• Clarify that the information and instructions provided be easy for the user to understand so they can correctly interpret the result provided by the device and to avoid misleading information.</li> <li>• Require devices intended for point of care testing, the information and the instructions provided by the manufacturer shall make clear the level of training and/or experience required by the user.</li> </ul>
<p><b>EP 15 continued....</b></p> <p>(7) An IVD medical device for self-testing must be designed and manufactured in a way that reduces, to the extent practicable, the risk of error in the use of the device, the handling of the sample and the presentation of results.</p>	<p><b>GSPR 19 continued.....</b></p> <p><b>GSPR 19.2</b> Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to:</p> <p>(a) ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and</p> <p>(b) reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.</p>	<p><b>Proposal 8(a)</b></p> <ul style="list-style-type: none"> <li>• Increase the scope to include devices for <b>point of care testing</b>.</li> <li>• Clarify the requirement that design and manufacture are to ensure that: <ul style="list-style-type: none"> <li>– the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary, after appropriate training and/or information</li> </ul> </li> </ul>

AUS Essential Principle 15 - IVDs	EU IVD Regulations only	Proposal 8 - Intent and <i>comments</i>
		– the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results, are minimised.

## Information to be provided with medical devices: AUS Essential Principle 13

### Proposal 9: Amend AUS Essential Principles 13.1

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
<p><b>EP 13 Information to be provided with medical devices</b></p> <p><b>EP 13.1 Information to be provided with medical devices – general</b></p> <p>(1) The following information must be provided with a medical device:</p> <p>(a) Information identifying the device;</p> <p>(b) Information identifying the manufacturer of the device;</p> <p>(c) Information explaining how to use the device safely; having regard to the training and knowledge of potential users of the device.</p> <p>(2) In particular:</p>	<p><b>MDR GSPR 23.1 and IVDR GSPR 20.1 General requirements regarding the information supplied by the manufacturer</b></p> <p>Each device shall be accompanied by the information needed to:</p> <ul style="list-style-type: none"> <li>– identify the device and</li> <li>– its manufacturer, and</li> <li>– by any safety and performance information relevant to the user or any other person, as appropriate.</li> </ul> <p>Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:</p>		<p>Proposal 9(a) <b>NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Require performance information relevant to the user or any other person be included.</li> </ul> <p><i>EU GSPRs related to electronic instructions for use (IFU) are outside the scope of this consultation.</i></p> <p><i>Electronic IFUs are part of our ongoing reforms. Once a policy decision has been made, these EU Regulations will be reconsidered for adoption, if appropriate.</i></p>

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
<p>(a) The information required by clause 13.3 must be provided with a medical device; and</p> <p>(b) If instructions for use of the device are required under subclause 13.4, the information mentioned in subclause 13.4(3) must be provided in those instructions.</p>			
<p><b>EP 13.1 continued....</b></p> <p>(3) The information:</p> <p>(a) Must be provided in English; and</p> <p>(b) May also be provided in any other language.</p> <p>Note: The information may also include diagrams or drawings.</p>	<p><b>MDR GSPR 23.1 and IVDR GSPR 20.1 continued...</b></p> <p>(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.</p>		<p><b>Proposal 9(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include the <b>option</b> for information required by EP 13 <b>to also</b> be provided in a machine-readable format.</li> </ul> <p><b>Proposal 9(b) AUS-specific:</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• The machine-readable format, if provided, must not interfere with the performance of the device or the device's ability to meet the Essential Principles.</li> </ul>
<p><b>EP 13.1 continued....</b></p> <p>(4) The format, content and location of the information must be appropriate for the device and its intended purpose.</p>	<p><b>MDR GSPR 23.1 and IVDR GSPR 20.1 continued...</b></p> <p>(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions</p>		<p><b>Proposal 9(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that consideration be given to the technical knowledge,</li> </ul>

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
<p>(5) Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high.</p>	<p>for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.</p>		<p>experience and training of the intended users.</p> <p><b>Proposal 9(c) – AUS-specific</b></p> <p>For AUS Essential Principle 13.1(5), in relation to the <b>legibility requirements</b>, we propose:</p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>To remove the minimum font size of 1mm, and instead include a reference to a FONT TYPE and SIZE, or equivalent, to be considered “legible” (e.g., at least equivalent to 8pt Times New Roman).</li> </ul> <p><b>Proposal 9(d) – AUS-specific</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Particular attention also to be given to the contrast of the text against the background for warnings, precautions and contraindications.</li> </ul>
<p><i>Refer to EP 13.4(1,2) – IFU requirements.</i></p>	<p><b>MDR GSPR 23.1 and IVDR GSPR 20.1 continued....</b></p> <p><b>Part (d)</b> <i>This clause relates to when instructions for use shall not be required, which aligns with the AUS EP 13.4(1,2). As such this clause has been included in the IFU requirements.</i></p>		<p><i>See Proposal 11: EP 13.4(1,2)</i></p>

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
<p>No equivalent AUS Essential Principle.</p>	<p><b>MDR GSPR 23.1 continued...</b></p> <p>(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.</p>	<p><b>IVDR GSPR 20.1 continued...</b></p> <p>(e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.</p>	<p><b>Proposal 9(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Where multiple devices, with the exception of devices intended for self-testing or point of care testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.</li> </ul> <p><b>Proposal 9(e) AUS-specific:</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>Devices intended for use by lay persons are to be excluded from being permitted to be supplied with a single copy of the instructions for use, as proposed above. Such devices are to be considered exempt, in the same manner that applies to devices intended for self-testing or near patient testing, in IVDR GSPR 20.1(e).</li> </ul>
<p>No equivalent AUS Essential Principle.</p>	<p><b>MDR GSPR 23.1 continued...</b></p> <p>(f) Instructions for use may be provided to the user in non-paper format (e.g. Electronic) to the</p>	<p><b>IVDR GSPR 20.1 continued....</b></p> <p>(f) When the device is intended for professional use only, instructions for use may be</p>	<p>No proposed changes, at this stage.</p> <p><i>EU GSPRs related to non-paper formats for instructions for use are outside the scope of this</i></p>

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
	extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.	provided to the user in non-paper format (e.g. Electronic), except when the device is intended for near-patient testing.	<i>consultation but are being considered as part of our ongoing reforms. Once a policy decision has been made, these EU Regulations will be reconsidered for adoption, if appropriate.</i>
<p><b>EP 13.1 continued....</b></p> <p>(6) If a symbol or identification colour that is not included in a medical device standard is used in the information provided with the device, or in the instructions for use of the device, the meaning of the symbol or identification colour must be explained in the information provided with the device or the instructions for use of the device.</p>	<p><b>MDR GSPR 23.1 and IVDR GSPR 20.1 continued....</b></p> <p>(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols (IVDR adds: taking into account the intended users). Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.</p>		No changes proposed.
<p>No equivalent within AUS Essential Principle 13.</p> <p><i>This requirement is stipulated under AUS Essential Principle 2.</i></p>	<p><b>MDR GSPR 23.1 and IVDR GSPR 20.1 - General requirements regarding the information supplied by the manufacturer</b></p> <p>(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.</p>		<p><b>Proposal 9(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Require information on any residual risks to be provided as limitation, contra-indications, precautions or warnings</li> </ul> <p><i>Although this is an addition to EP 13.1, it is not a new requirement. Informing users of residual risks is a requirement of AUS Essential Principle 2.</i></p>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	IVDR GSPR 20.1 continued...	<b>Proposal 9(a) NEW</b>

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
		<p>(i) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of <a href="#">Regulation (EC) No 1272/2008</a> shall apply.</p> <p>Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use.</p>	<p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>Require relevant hazard pictograms and labelling requirements (as required by any Australian legislation) for any device containing substances or mixtures which may be considered as dangerous goods.</li> </ul> <p><i>Depending on legislative drafting requirements, reference may be made to the regulations and requirements for hazardous chemical labels in Australia, such as the <a href="#">Globally Harmonized System (GHS) of Classification and Labelling of Chemicals<sup>2</sup></a> for the classification of hazardous chemicals.</i></p>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	<p><b>IVDR GSPR 20.1</b></p> <p>(j) The provisions of <a href="#">Regulation (EC) No 1907/2006</a> on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use. 5.5.2017 L 117/266 Official Journal of the European Union EN</p>	<p><b>Proposal 9(a) NEW</b></p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>Require compliance with relevant safety requirements related to dangerous substances.</li> </ul> <p><i>Reference may be made to the regulations and requirements for hazardous chemical labels, in</i></p>

<sup>2</sup> Globally Harmonised System (GHS) of Classification and Labelling of Chemicals: <http://unece.org/ghs-rev7-2017>



AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
			<i>Australia, such as those detailed in Safe Work Australia's <a href="#">Information on hazardous chemicals</a><sup>3</sup>.</i>
<p><b>EP 13.2 Information to be provided with medical devices (Location of information)</b></p> <p>(1) Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself.</p> <p>(2) If it is not practicable to comply with subclause (1) in relation to the provision of the information, the information must be provided:</p> <p>(a) On the packaging used for the device; or</p> <p>(b) In the case of devices that are packaged together because individual packaging of the devices for supply is not practicable—on the outer packaging used for the devices.</p> <p>(3) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required</p>	<p><b>MDR GSPR 23.1(b) and IVDR GSPR 20.1(b)</b></p> <p>The information required on the label shall be provided on the device itself.</p> <p>If this is not practicable or appropriate,</p> <p>Some or all of the information may appear on the packaging for each unit.</p> <p>If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.</p>		No changes proposed.

<sup>3</sup> Information on hazardous chemicals: <https://www.safeworkaustralia.gov.au/safety-topic/hazards/chemicals/labelling-hazardous-chemicals/information-hazardous-chemical-labels>

AUS Essential Principle 13.1 – 13.2	EU MD Regulations	EU IVD Regulations	Proposal 9 - Intent and <i>comments</i>
<p>under sub regulation 10.2 (1) or clause 13.3,</p> <p>(a) For a medical device that is not software—the information must be provided on a leaflet supplied with the device; or</p> <p>(b) For a medical device that is software—the information must be provided on a leaflet supplied with the device or the information must be provided electronically.</p> <p>(4) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under clause 13.4, the information must be provided in a printed document or using other appropriate media.</p>			

### Proposal 10: Amend AUS Essential Principles 13.3 (General labelling)

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
<p><b>EP 13.3 Information to be provided with medical devices – particular requirements</b></p> <p><b>EP 13.3 The information mentioned in the following table must be provided with a medical device.</b></p>	<p><b>MDR GSPR 23.2 and IVDR GSPR 20.2 - Information on the label</b></p> <p>The label shall bear all of the following particulars:</p>		<p>No proposed change.</p>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
<p>No equivalent AUS Essential Principles.</p>	<p><b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued...</b></p> <p>(a) the name of the device</p>		<p><b>Proposal 10(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include the name of the device.</li> </ul>
<p><b>EP 13.3 Item:</b></p> <p>1. The manufacturer's name, or trading name, and address</p>	<p><b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued....</b></p> <p>(c) the name, registered trade name or registered trademark of the manufacturer and the address of its registered place of business;</p>		<p><b>Proposal 10(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that the manufacturer's address must be their registered place of business (i.e., not a PO Box)</li> </ul>
<p><b>EP 13.3 Item:</b></p> <p>2. The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)</p> <p>3. Sufficient information to enable a user to identify the device, or if relevant the contents of packaging</p>	<p><b>MDR GSPR 23.2 continued....</b></p> <p>(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;</p>	<p><b>IVDR GSPR 20.2 continued....</b></p> <p>(b) the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;</p> <p>(j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;</p>	<p><b>Proposal 10(a) NEW</b></p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that information be included, where relevant, such as an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package.</li> </ul>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
<p><b>EP 13.3 Item:</b></p> <p>4. Any particular handling or storage requirements applying to the device</p>	<p><b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued....</b></p> <p>(k) an indication of any special storage and/or handling condition that applies;</p>		<p>No proposed changes.</p>
<p><b>EP 13.3 Item:</b></p> <p>5. Any warnings, restrictions, or precautions that should be taken, in relation to use of the device</p>	<p><b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued....</b></p> <p>(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;</p>		<p><b>Proposal 10(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that critical information, that needs to be brought to the immediate attention of the user, or any other person, to be clearly evident.</li> <li>• Clarify that critical information may be kept to a minimum, in which case more detailed information shall appear in the instructions for use, taking into account the intended users.</li> </ul>
<p><b>EP 13.3 Item:</b></p> <p>6. Any special operating instructions for the use of the device.</p>	<p>No equivalent EU GSPR in the MDR.</p>	<p><b>IVDR GSPR 20.2 continued....</b></p> <p>(o) where applicable, any particular operating instructions</p>	<p>No changes proposed.</p>
<p><b>EP 13.3 Item:</b></p> <p>7. If applicable, an indication that the device is intended for a single use only</p>	<p><b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued....</b></p> <p>MDR (n) and IVDR (p) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union</p>		<p>No changes proposed.</p>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.2 continued...</b> (o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;	No equivalent EU GSPR in the IVDR.	No changes proposed.  <i>The EU MDR outlines the provisions around reprocessing of single-use devices in Article 17.</i>  <i>We currently have no such provisions for reprocessing of single-use devices within our Regulations. Regulation 1.5 applies to Refurbishment (Act s3(1)).</i>
<b>EP 13.3 Item:</b> 8. If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional	<b>MDR GSPR 23.2 continued.....</b> (p) if the device is custom-made, the words 'custom-made device';	No equivalent EU GSPR in the IVDR.	No changes proposed.
<b>EP 13.3 Item:</b> 9. If applicable, an indication that: (a) If the device is a medical device other than an IVD medical device – the device is intended for pre-market clinical investigation; (b) If the device is an IVD medical device—the device is intended for performance evaluation only	<b>MDR GSPR 23.2 continued.....</b> (q) an indication that the device is a <b>medical device</b> . If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation'	<b>IVDR GSPR 20.2 continued....</b> (e) an indication that the device is an <b>in vitro diagnostic medical device</b> , or if the device is a 'device for performance study', an indication of that fact;	<b>Proposal 10(a) NEW</b>  <b>For all devices:</b> <ul style="list-style-type: none"> <li>• Include an indication that the device is a medical device or an IVD device, as applicable.</li> </ul>
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.2 continued.....</b>	No equivalent EU GSPR in the IVDR.	<b>Proposal 10(a) NEW</b>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
	<p><b>23.2 (r)</b> in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;</p>		<p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>For devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, include information on the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action.</li> </ul>
<p><b>EP 13.3 Item:</b></p> <p>10. For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device</p>	<p><b>MDR GSPR 23.2 continued.....</b></p> <p>(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method;</p>	<p><b>IVDR GSPR 20.2 continued....</b></p> <p>(l) where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;</p>	<p><b>Proposal 10(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Devices with a specific microbial state, to include a statement indicating any special microbial state or state of cleanliness.</li> </ul> <p><i>Note: "Specific microbial state" is proposed for adopting, for both IVD devices and other medical devices, under EP 8.3/MDR GSPR 11.3/IVDR GSPR 11.2.</i></p> <p><i>The EU MDR doesn't appear to have an equivalent labelling requirement specifically for non-IVD devices with a "specific microbial state,".</i></p>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
			<i>We propose to also apply this IVDR labelling requirement to non-IVD devices for which a specific microbial state is applicable.</i>
<b>EP 13.3 Item:</b> 11. The batch code, lot number or serial number of the device	<b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued....</b> <b>MDR (g) and IVDR (f)</b> the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;		No changes proposed.
<b>EP 13.3 Item:</b> 12. If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used	<b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued....</b> <b>MDR (i) and IVDR (h)</b> an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;		<b>Proposal 10(a)</b> <b>For all devices:</b> <ul style="list-style-type: none"> <li>• Provide clarity by adding “without degradation of performance”.</li> </ul>
<b>No equivalent AUS Essential Principles.</b>	<b>MDR GSPR 23.2 continued...</b> (e) where applicable, an indication that the device contains or incorporates: <ul style="list-style-type: none"> <li>– A medicinal substance, including a human blood or plasma derivative, or</li> <li>– Tissues or cells, or their derivatives, of human origin, or</li> <li>– Tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;</li> </ul>	<b>No equivalent EU GSPR in the IVDR.</b>	<b>Proposal 10(a) NEW</b> <b>For non-IVD devices:</b> <ul style="list-style-type: none"> <li>• Labelling to indicate that the device contains or incorporates:               <ul style="list-style-type: none"> <li>– A medicinal substance, including human blood or plasma or derivatives</li> <li>– Tissue or cells or animal origin, or their derivatives</li> </ul> </li> </ul> <i>Note: We will not adopt the clause regarding tissues, cells, or their derivatives, of human origin for non-</i>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
			<i>IVD devices, as these fall under our Biologicals Regulatory Framework.</i>
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued...</b> (d) if the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative;		No proposed changes.
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.2 continued...</b> (f) where applicable, information labelled in accordance with Section 10.4.5.;	No equivalent EU GSPR in the IVDR.	No proposed changes. <i>Refer to comments under AUS EP 7.5 related to EU MDR GSPR 10.4.1</i>
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.2 and IVDR GSPR 20.2 continued...</b> <b>MDR (h) and IVDR (g)</b> The UDI carrier, as referred to in Article 24 and Part C of Annex VI;		<b>Proposal 10(a) NEW</b> <b>For all devices:</b> • Include the unique device identifier (UDI) <i>This requirement is being progressed as part of our existing UDI reforms project.</i>
<b>EP 13.3 Item:</b> 13. If the information provided with the device does not include the information mentioned in item 12—a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the	<b>MDR GSPR 23.2 continued...</b> (j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or	<b>IVDR GSPR 20.2 continued...</b> (i) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number,	No changes proposed.



AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
device, provided the date is clearly identifiable)	serial number, provided the date is clearly identifiable;	provided the date is clearly identifiable;	
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.2 continued...</b> (s) For active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.	No equivalent EU GSPR in the IVDR.	<b>Proposal 10(a) NEW</b> <b>For non-IVD devices:</b> <ul style="list-style-type: none"> <li>• Active implantable to have the serial number.</li> <li>• Other implantable devices to have the serial number or lot number</li> </ul>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	<b>IVDR GSPR 20.2 continued....</b> (n) if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted	No proposed change. <i>EU GSPRs related to electronic instructions for use are outside the scope of the current consultation.</i> <i>Electronic IFUs are part of our ongoing reforms. Once a policy decision has been made, these EU Regulations will be reconsidered for adoption, if appropriate.</i>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	<b>IVDR GSPR 20.2 continued....</b> (q) if the device is intended for self-testing or near-patient testing, an indication of that fact;	<b>Proposal 10(a) NEW</b> <b>For IVD devices:</b> <ul style="list-style-type: none"> <li>• If the device is intended for self-testing or near-patient testing, an indication of that fact</li> </ul>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	<b>IVDR GSPR 20.2 continued....</b> (r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;	<b>Proposal 10(a) NEW</b> <b>For IVD devices:</b> <ul style="list-style-type: none"> <li>• Rapid assays not intended for self-testing or point-of-care testing must explicitly exclude their use for such purposes.</li> </ul>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	<b>IVDR GSPR 20.2 continued....</b> (s) Where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;	<b>Proposal 10(a) NEW</b> <b>For IVD devices:</b> <ul style="list-style-type: none"> <li>• Where components of a kit are available as separate devices, each of those devices must comply with the relevant Essential Principles, including EP 13.</li> </ul>
No equivalent AUS Essential Principles.	No equivalent EU GSPR in the MDR.	<b>IVDR GSPR 20.2 continued....</b> (t) The devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the	<b>Proposal 10(a) NEW</b> <b>For IVD devices:</b> <ul style="list-style-type: none"> <li>• The device and any separate components are to be traceable in terms of batches.</li> <li>• As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging.</li> </ul>

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
		device itself and/or, where appropriate, on the sales packaging;	
<p>No equivalent AUS Essential Principles.</p>	<p>No equivalent EU GSPR in the MDR.</p>	<p><b>IVDR GSPR 20.2 continued....</b></p> <p>(u) The label for devices for self-testing shall bear the following particulars:</p> <p>(i) The type of specimen(s) required to perform the test (e.g. Blood, urine or saliva);</p> <p>(ii) The need for additional materials for the test to function properly;</p> <p>(iii) Contact details for further advice and assistance.</p> <p>The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.</p>	<p><b>Proposal 10(a) NEW</b></p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Labelling requirements for self-testing IVD devices to include the following particulars <ul style="list-style-type: none"> <li>– The type of specimen(s) required to perform the test (e.g. Blood, urine or saliva);</li> <li>– The need for additional materials for the test to function properly;</li> <li>– Contact details for further advice and assistance</li> </ul> </li> <li>• The name of the device for self-testing is not to reflect an intended purpose other than that intended by the manufacturer.</li> </ul>
<p>No equivalent AUS Essential Principles.</p> <p><i>These GSPRs are specific to the information on the packaging of devices supplied sterile.</i></p>	<p><b>MDR GSPR 23.3 and IVDR GSPR 20.3 Information on the packaging which maintains the sterile condition of a device ('sterile packaging')</b></p> <p>The following particulars shall appear on the sterile packaging:</p> <p>(a) an indication permitting the sterile packaging to be recognised as such,</p>	<p><b>Proposal 10(a) NEW</b></p> <p><i>The requirements within GSPRs 23.2(MDR) and 20.3(IVDR) are specifically regarding information that must be included on the packaging of devices supplied sterile.</i></p>	

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
	(b) a declaration that the device is in a sterile condition, (c) the method of sterilisation, (d) the name and address of the manufacturer, (e) a description of the device,		<p><b>For all devices supplied sterile:</b></p> <ul style="list-style-type: none"> <li>• An indication permitting the sterile packaging to be recognised as such,</li> <li>• A declaration that the device is in a sterile condition,</li> <li>• The method of sterilisation,</li> <li>• The name and address of the manufacturer,</li> <li>• A description of the device,</li> <li>• The month and year of manufacture,</li> <li>• An unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and</li> <li>• An instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.</li> </ul> <p><b>For non-IVD devices supplied sterile:</b></p> <ul style="list-style-type: none"> <li>• If the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’.</li> <li>• If the device is custom-made, the words ‘custom-made device’.</li> </ul>
(f) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’, (g) if the device is custom-made, the words ‘custom-made device’,	<p style="color: red;">No equivalent EU GSPR in the IVDR.</p>		
(h) the month and year of manufacture, (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.	(f) the month and year of manufacture, (g) an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order, (h) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.		

AUS Essential Principle 13.3	EU MD Regulations	EU IVD Regulations	Proposal 10 - Intent and <i>comments</i>
<b>EP 13.3 Item:</b> 14. If applicable, the words 'for export only'	No equivalent EU GSPR in the MDR.	No equivalent EU GSPR in the IVDR.	No changes proposed.

### Proposal 11: AUS Essential Principle 13.4 – Instructions for use (excluding Item 29 – IVDs only)

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<b>13.4 Instructions for use</b> (1) Instructions for the use of a medical device must be provided with the device.	<b>MDR GSPR 23.1 and IVDR GSPR 20.1 General requirements regarding the information supplied by the manufacturer</b> (d) Instructions for use shall be provided together with devices.		No proposed changes.
<b>EP 13.4 continued....</b> (2) However, instructions for use of a medical device need not be provided with the device, or may be abbreviated, if: (a) The device is a Class I medical device, a Class IIa medical device or a Class I IVD medical device; and (b) The device can be used safely for its intended purpose without instructions.	<b>MDR GSPR 23.1 continued.....</b> (d) By way of exception, instructions for use shall not be required for Class I and IIa devices if such devices can be used safely and as intended by the manufacturer without any such instructions and unless provided for elsewhere in this Section.	<b>IVDR GSPR 20.1 continued.....</b> (d) However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.	No proposed changes.

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p><b>EP 13.4 continued....</b></p> <p>(3) Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.</p>	<p><b>MDR GSPR 23.4 Information in the instructions for use</b></p> <p>The instructions for use shall contain all of the following particulars:</p>	<p><b>IVDR GSPR 20.4 Information in the instructions for use</b></p> <p><b>20.4.1</b> The instructions for use shall contain all of the following particulars:</p>	<p>No proposed changes.</p>
<p><b>EP 13.4 (3) Item:</b></p> <p><b>No equivalent AUS Essential Principles.</b></p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(a) The particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><b>23.2(a)</b> name or trade name of the device;</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(a) the name, registered trade name of the device</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include the name of the device</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>1. The manufacturer's name, or trading name, and address</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(a) The particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><b>23.2(c)</b> the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business.</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(ad) the name, registered trade or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;</p>	<p><b>Proposal 11(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Clarify that the manufacturer's address has to be their registered place of business</li> </ul> <p>For IVD devices:</p> <ul style="list-style-type: none"> <li>• Provide contact details for users to obtain technical assistance, including a telephone number and/or fax number and/or website address.</li> </ul> <p><i>The following clauses of MDR 23.4(a) align with the following EPs:</i></p>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
			<p>(e) – Refer to EP 13.4(3) Items 24, 25, 25A</p> <p>(k) – Refer to EP 13.4(3) Item 7</p> <p>(l) – Refer to EP 13.4(3) Item 11</p> <p>(n) – Refer to EP 13.4(3) Item 8</p>
<p>No equivalent AUS Essential Principles.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><i>For reference:</i></p> <p><b>23.2 (f)</b> where applicable, information labelled in accordance with Section 10.4.5</p>	<p>No equivalent EU GSPR in the IVDR.</p>	<p>No proposed changes.</p>
<p>No equivalent AUS Essential Principles.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><b>23.2 (r)</b> in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible</p>	<p>No equivalent EU GSPR in the IVDR.</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>For devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, include: <ul style="list-style-type: none"> <li>– the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for</li> </ul> </li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
	<p>for achieving the principal intended action;</p> <p><b>MDR GSPR 23.4 continued...</b></p> <p>(t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side-effects and risks relating to overdose;</p>		<p>achieving the principal intended action</p> <p>– warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side-effects and risks relating to overdose;</p>
<p><b>EP 13.4 (3) Item:</b></p> <p>2. The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(u) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(c) the device's intended purpose</p> <p>(e) the intended user, as appropriate (e.g. Self-testing, near patient and laboratory professional use, healthcare professionals);</p>	<p><b>Proposal 11(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include indications and contra-indications, where applicable.</li> </ul> <p><b>For IVD devices:</b></p> <p><i>Additional specific details from IVDR GSPR 20.4.1(c) are also being proposed for IVD devices under EP 13.3(4) Item 29.</i></p>



AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p><b>EP 13.4 (3) Item:</b></p> <p>3. Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro surgical devices or magnetic field interference from magnetic resonance imaging devices)</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:</p> <ul style="list-style-type: none"> <li>– Warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,</li> </ul>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p><b>Proposal 11(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Inform the user and/or patient of any residual risks, where relevant.</li> <li>• Provide information to allow the user to inform patients about any residual risks,</li> <li>• Examples to be included for clarity, such as: <ul style="list-style-type: none"> <li>– External electrical and electromagnetic effects,</li> <li>– Electrostatic discharge radiation associated with diagnostic or therapeutic procedures,</li> <li>– Pressure, humidity, or temperature</li> </ul> </li> </ul> <p><i>Remaining clauses of MDR 23.4(s) are under EP 13.4(3) Items 5, 22 and 24.</i></p>
<p><b>EP 13.4 (3) Item:</b></p> <p>4. Information about the intended performance of the device and any undesirable</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(c) where applicable, a specification of the clinical benefits to be expected.</p>	<p><b>IVDR GSPR 20.4.1 (w) and (x)</b></p> <p><i>Refer to EP 13.4(3) Item 29 (f) and (g).</i></p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Where applicable, a specification of the clinical benefits expected.</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
side effects caused by use of the device.	<p>(d) where applicable, links to the summary of safety and clinical performance referred to in Article 32;</p> <p>(e) the performance characteristics of the device;</p>		<ul style="list-style-type: none"> <li>Where applicable, links to the summary of safety and clinical performance.</li> <li>The performance characteristics of the device.</li> </ul> <p><i>Requirements for IVD devices are proposed under EP 13.4(3) Item 29 (f) and (g).</i></p>
<p><b>EP 13.4 (3) Item:</b></p> <p>5. Any contraindications, warnings, restrictions on use, or precautions that may apply in relation to use of the device</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;</p> <p>(s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:</p> <p>– Warnings, precautions and/or measures to be taken as regards</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(n) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate:</p> <p>(iii) warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment</p> <p>(iv) precautions related to materials incorporated into the</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>Informing the user and/or patient of any residual risks, where relevant,</li> <li>Provide information to allow the user to inform patients about any residual risks.</li> <li>Include information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device.</li> <li>Include, where appropriate:</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
	<p>the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,</p> <p>– Precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;</p>	<p>device that contain or consist of carcinogenic, mutagenic, toxic to reproduction substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,</p>	<p>– warnings, precautions and/or measures to be taken as regards the risks of interference, such as electromagnetic interference, emitted by the device affecting other equipment, posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures</p> <p>– precautions related to materials incorporated into the device that contain or consist of carcinogenic, mutagenic, toxic to reproduction substances, or endocrine disrupting substances</p> <p>– precautions related to material incorporated into the device that could results in sensitisation or an allergic reaction</p> <p><i>Remaining clauses of MDR GSPR 23.4(s) are under EP 13.4(3) Items 3, 22 and 24.</i></p> <p><i>Remaining clauses of IVDR GSPR 20.4.1(n) are included under other Items in EP 13.4(3) as outlined below:</i></p> <p><i>(i) – EP, Item 22</i></p> <p><i>(ii) – EP, Item 3</i></p> <p><i>(v) – EP, Item 8</i></p>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
			<i>(vi) – EP, Item 20</i>
<p><b>EP 13.4 (3) Item:</b></p> <p>6. Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging</p>	<p><b>MDR GSPR 23.1 General requirements....</b></p> <p>Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate.</p> <p>Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(b) the details strictly necessary for the user to uniquely identify the device</p> <p><b>IVDR GSPR 20.1</b></p> <p>Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate.</p> <p>Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website</p>	No proposed changes.
<p><b>EP 13.4 (3) Item:</b></p> <p>7. Any particular handling or storage conditions</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><b>23.2 (k)</b> an indication of any special storage and/or handling condition that applies</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(k) an indication of any special storage (e.g. Temperature, light, humidity, etc.) And/or handling conditions which apply</p>	No proposed changes.

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p><b>EP 13.4 (3) Item:</b></p> <p>8. If applicable, an indication that the device is intended for a single use only</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><b>23.2 (n)</b> if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;</p> <p><b>MDR GSPR 23.4 continued...</b></p> <p>(p) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, here such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. No instructions for use are required, this information shall be made available to the user upon request</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(n) part (v) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Include information characteristics and technical factors that could pose a risk if the device were to be re-used.</li> <li>• Provide information is to be based on sufficiently detailed information in the manufacturer's risk management documentation.</li> <li>• If no instructions for use are required with the device the information is to be made available to the user upon request.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>9. If applicable, an indication that the device has been</p>	<p><b>No equivalent EU GSPR in the MDR.</b></p>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p>No proposed changes.</p>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p>custom-made for a particular individual or health professional and is intended for use only by that individual or health professional.</p>			
<p><b>EP 13.4 (3) Item:</b></p> <p>10. If applicable, an indication that:</p> <p>(a) If the device is a medical device other than an IVD medical device –the device is intended for pre-market clinical investigation;</p> <p>(b) If the device is an IVD medical device—the device is intended for performance evaluation only</p>	<p><b>No equivalent EU GSPR in the MDR.</b></p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(d) an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact.</p>	<p>No proposed changes.</p> <p><i>The EU MDR only requires this information to be on the label.</i></p>
<p>EP 13.4 (3) Item:</p> <p>11. For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device</p>	<p><b>No equivalent EU GSPR in the MDR.</b></p>	<p><i>Refer to below, under to EP 13.4(3) Item 13.</i></p>	<p>No proposed changes.</p>
<p><b>EP 13.4 (3) Item:</b></p> <p>12. For a device that is intended by the manufacturer to be supplied in a sterile state:</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(m) if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of</p>	<p><b>Proposal 11(a)</b></p> <p><b>For all devices supplied sterile:</b></p> <ul style="list-style-type: none"> <li>• If the device is supplied sterile, include instructions in the event of the sterile packaging being</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p>(a) An indication that the device is sterile; and</p> <p>(b) Information about what to do if sterile packaging is damaged and;</p> <p>(c) If appropriate, instructions for resterilisation of the device.</p>	or unintentionally opened before use;	the sterile packaging being damaged before use;	unintentionally opened or damaged before use.
<p><b>EP 13.4 (3) Item:</b></p> <p>13. For a medical device that is intended by the manufacturer to be sterilised before use— instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(r) details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;</p>	<p><b>Proposal 11(a)</b></p> <p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>For IVD devices intended to be sterilised before use include information, where relevant, of any preparatory treatment or handling of the device needed before it is ready for use.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>14. Any special operating instructions for the use of the device</p>	No equivalent EU GSPR in the MDR.	No equivalent EU GSPR in the IVDR.	No proposed changes.
<p><b>EP 13.4 (3) Item:</b></p> <p>15. Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(s) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For all devices:</b></p> <p>EP 13.4(3) Item 15:</p> <ul style="list-style-type: none"> <li>Include any limitation on the use of calibrators and controls, such as if</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p>calibration (if any) needed to ensure that the device operates properly and safely during its intended life</p>	<p>manufacturer, together with, where relevant</p> <ul style="list-style-type: none"> <li>– Information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and</li> </ul>	<ul style="list-style-type: none"> <li>– Information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;</li> <li>– Methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.</li> </ul>	<p>they are suitable for a dedicated instrument only.</p> <ul style="list-style-type: none"> <li>• Include methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.</li> </ul>
<p>16. Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life</p>	<ul style="list-style-type: none"> <li>– Methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices</li> <li>– Details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,</li> <li>– Identification of any consumable components and how to replace them</li> </ul>	<ul style="list-style-type: none"> <li>– Details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;</li> <li>– Identification of any consumable components and how to replace them</li> </ul>	<p><b>Proposal 11(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include information on preparatory cleaning or disinfection, where relevant</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>17. Information about any treatment or handling needed before the device can be used</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <ul style="list-style-type: none"> <li>(i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;</li> </ul>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p><b>Proposal 11(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Details of any preparatory treatment or handling of the device before or during use.</li> <li>• Examples may be included, to provide additional clarity.</li> </ul>



AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p><b>EP 13.4 (3) Item:</b></p> <p>18. For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose – sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(q) for devices intended for use together with other devices and/or general purpose equipment:</p> <ul style="list-style-type: none"> <li>– Information to identify such devices or equipment, in order to obtain a safe combination, and/or</li> <li>– Information on any known restrictions to combinations of devices and equipment;</li> </ul>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(j) for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:</p> <ul style="list-style-type: none"> <li>– Information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or</li> <li>– Information on any known restrictions to combinations of devices and equipment.</li> </ul>	<p><b>Proposal 11(a)</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include information on any known restrictions to combinations of devices and equipment.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>19. For an implantable device – information about any risks associated with its implantation</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;</p>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For devices that are implantable:</b></p> <ul style="list-style-type: none"> <li>• Include qualitative and quantitative information on the materials and substances to which patients can be exposed.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>20. For a reusable device:</p> <p>(a) Information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection,</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(n) <b>part (vi)</b> if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation.</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For all devices that are reusable:</b></p> <ul style="list-style-type: none"> <li>• Require re-sterilisation methods provided with the device to be <b>validated methods.</b></li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p>packaging and, if appropriate, re-sterilisation of the device); and</p> <p>(b) An indication of the number of times the device may be safely reused</p>	<p>appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. Signs of material degradation or the maximum number of allowable reuses</p>	<p>Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses</p>	<ul style="list-style-type: none"> <li>• Include information to allow users to know when a device should no longer be used, with example/s.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>21. For a medical device that is intended by the manufacturer to emit radiation for medical purposes—details of the nature, type, intensity and distribution of the radiation emitted</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(r) if the device emits radiation for medical purposes:</p> <ul style="list-style-type: none"> <li>– Detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,</li> <li>– The means of protecting the patient, user, or other person from unintended radiation during use of the device;</li> </ul>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices intended to emit radiation for medical purposes:</b></p> <ul style="list-style-type: none"> <li>• Include information on protection for the patient, user and other persons from unintended radiation during use of the device.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>22. Information about precautions that should be taken by a patient and the user if the performance of the device changes.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions,</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(n) <b>part (i)</b> warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,</p>	<p><b>Proposal 11(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Include information covering, where appropriate, warnings, precautions and/or measures to be taken in the event of malfunction of the device that may affect safety.</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
	<p>contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:</p> <p>– Warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety</p>		<p><b>For IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Include information covering, where appropriate, warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>23. Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions</p>	<p><b>No equivalent EU GSPR in the MDR.</b></p>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p>No proposed changes.</p>
<p><b>EP 13.4 (3) Item:</b></p> <p>24. Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(s) information that allows the user and/or patient to be informed of any warnings, precautions, contra- indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use</p>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p><b>Proposal 11(a)</b></p> <p><b>For non-IVD devices administering medicinal products:</b></p> <ul style="list-style-type: none"> <li>• The scope is to be expanded to also include <b>biological products or substances</b> to be administered.</li> <li>• Information to be provided to also include any <b>incompatibility</b> in the choice of substances to be delivered</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
	<p>regarding the device. The information shall cover, where appropriate:</p> <ul style="list-style-type: none"> <li>– If the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered</li> <li>– Warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and</li> </ul>		<p>or other necessary warnings or precautions.</p> <p><i>Requirements for devices incorporating any stable derivative of human blood or blood plasma, are under EP 13.4(3) Item 25</i></p> <p><i>Requirements for devices incorporating tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable are under EP 13.4(3) Item 25A.</i></p>
<p><b>EP 13.4 (3) Item:</b></p> <p>25. Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated or intended to be incorporated into the device as an integral part of the device</p> <p><b>EP 13.4 (3) Item:</b></p> <p>25A. For a medical device to which clause 5.5 of Schedule 2 applies (other than an IVD medical device), information</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(c) (a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2:</p> <p><b>23.2 (e)</b> where applicable, an indication that the device contains or incorporates:</p> <ul style="list-style-type: none"> <li>– A medicinal substance, including a human blood or plasma derivative, or</li> <li>– Tissues or cells, or their derivatives, of human origin, or</li> </ul>	<p><b>No equivalent EU GSPR in the IVDR.</b></p>	<p>No proposed changes.</p> <p><i>Non-IVD devices that incorporate tissues or cells, or their derivatives, of human origin, are not regulated as medical devices. Such products fall under the Australian Biologicals Regulatory Framework..</i></p> <p><b>Legislative changes to Item 25A</b></p> <p><i>As part of our classification of devices review, Item25A within EP 13.4(3) was amended, following consultation, to remove reference to microbial and recombinant substances.</i></p>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p>to the effect that the device contains or incorporates any of the following:</p> <p>(a) non-viable tissues, or cells, of animal origin;</p> <p>(b) derivatives of tissues or cells referred to in paragraph (a)</p>	<p>– Tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;</p>		
<p><b>EP 13.4 (3) Item:</b></p> <p>26. Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:</p> <p>– Infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and</p> <p>– Physical hazards such as from sharps.</p> <p>If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(ac) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:</p> <p>(i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;</p> <p>(ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation;</p> <p>(iii) physical hazards such as explosion.</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For all devices:</b></p> <p>If there are risks associated with the disposal of the device, its accessories, consumables or waste products, where appropriate include:</p> <ul style="list-style-type: none"> <li>• warnings and precautions on the safe disposal of the device, its accessories and the consumables used with it, and any related waste product, including: <ul style="list-style-type: none"> <li>– infection or microbial hazards</li> <li>– physical hazards</li> <li>– environmental hazards</li> <li>– clarity provided through relevant examples</li> </ul> </li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
			<ul style="list-style-type: none"> <li>identified and tested disposal procedures for the device, and any related waste products.*</li> </ul> <p><i>*MDR GSPR 14.7 and IVDR GSPR 13.6 both require that “manufacturers identify and test procedures and measures as a result of which their devices can be safely disposed of after use. Such procedures shall be described in the instructions for use.”</i></p> <p><i>While the EU GSPRs do not explicitly list this requirement under their equivalent labelling requirements, we consider it important to include this requirement specifically under EP 13.</i></p> <p><i>This is also addressed under our existing AUS Essential Principle 9.2(h), which requires devices to facilitate safe disposal of the device and waste products.</i></p>
<p><b>EP 13.4 (3) Item:</b></p> <p>27. Information about the degree of accuracy claimed if the device has a measuring function</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(h) specifications the user requires to use the device appropriately, e.g. If the device has a measuring function, the degree of accuracy claimed for it</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(w) analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-</p>	<p><b>Proposal 11(a)</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>Require information to be included on specifications the user needs to use the device appropriately, such as, (but not limited to) devices with a measuring function, the degree of accuracy claimed for it.</li> </ul> <p><b>For IVD devices:</b></p>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
		reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;	<ul style="list-style-type: none"> <li>Require information to be included on analytical performance characteristics, including analytical sensitivity, analytical specificity, trueness, precision, accuracy, limits of detection and measurement range, measuring range, linearity and information about the use of available reference measurement procedures and materials by the user.</li> </ul>
<p><b>EP 13.4 (3) Item:</b></p> <p>28. Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(k) where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;</p>	No proposed changes.
Refer to <a href="#">Proposal 12</a> for EP 13.4(3) Item 29 (IVDs only)			
<p><b>EP 13.4 (3) Item:</b></p> <p>30. For an adaptable medical device, instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles</p>	No equivalent EU GSPR in the MDR.	No equivalent EU GSPR in the IVDR.	No proposed changes.

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
<p><b>EP 13.4 (3) Item:</b></p> <p>31. For a medical device production system, instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles</p>	<p>No equivalent EU GSPR in the MDR.</p>	<p>No equivalent EU GSPR in the IVDR.</p>	<p>No proposed changes.</p>
<p>No equivalent AUS Essential Principles.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories</p>	<p>No equivalent EU GSPR in the IVDR.</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Include information, where applicable, to allow healthcare professionals to: <ul style="list-style-type: none"> <li>– Verify if the device is suitable</li> <li>– Select the corresponding software and accessories.</li> </ul> </li> </ul>
<p>No equivalent AUS Essential Principles.</p>	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.</p>	<p>No equivalent EU GSPR in the IVDR.</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Include information, if appropriate, on whether the device can be reused only if it is refurbished (as</li> </ul>



AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
			defined in Regulation 1.5 <sup>4</sup> ) under the responsibility of the manufacturer to comply with the requirements of the AUS Essential Principles.
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.4 continued...</b> (w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional	No equivalent EU GSPR in the IVDR.	<b>Proposal 11(a) NEW</b> <b>For non-IVD devices:</b> <ul style="list-style-type: none"> <li>For devices <b>intended for use by lay persons</b>, include the circumstances in which the user should consult a healthcare professional.</li> </ul> <i>This requirement also applies to IVD devices, and is re-iterated in EP 13.4(3)29 under the NEW proposals for adoption from IVDR GSPR 20.4.2 (f).</i>
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.4 continued...</b> (x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;		Out-of-scope. <i>Devices without an intended medical purpose are being considered under a separate reforms project.</i>
No equivalent AUS Essential Principles.	<b>MDR GSPR 23.4 continued...</b>	<b>IVDR GSPR 20.4.1 continued....</b>	<b>Proposal 11(a) NEW</b>

<sup>4</sup> Therapeutic Goods (Medical Devices) Regulation 2002, Part 1.5 Refurbishment

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
	(y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use	(ae) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;	<p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include the date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use.</li> </ul> <p><i>We do not propose to adopt the additional requirement of the IVDR GSPR 20.4.1(ae) to also include the additional requirement to include a clear indication of the introduced modifications.</i></p>
No equivalent AUS Essential Principles.	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(af) a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For all devices:</b></p> <ul style="list-style-type: none"> <li>• Include information to inform users and/or patients about reporting adverse events.</li> </ul>
No equivalent AUS Essential Principles.	<p><b>MDR GSPR 23.4 continued...</b></p> <p>(ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security</p>	<p><b>IVDR GSPR 20.4.1 continued....</b></p> <p>(ah) security measures, including protection against unauthorised access, necessary to run the software as intended.</p>	<p><b>Proposal 11(a) NEW</b></p> <p><b>For non-IVD devices:</b></p> <ul style="list-style-type: none"> <li>• Include requirements necessary to operate devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum</li> </ul>

AUS Essential Principle 13.4	EU MD Regulations (GSPR)	EU IVD Regulations (GSPR)	Proposal 11 - Intent and <i>comments</i>
	measures, including protection against unauthorised access, necessary to run the software as intended.		<p>requirements for hardware, IT network characteristics and IT.</p> <p>For all devices:</p> <ul style="list-style-type: none"> <li>• Include security measures, including protection against unauthorised access, necessary to run the software as intended.</li> </ul> <p><i>While these are new additions to EP 13.4(3), they are not new requirements, as they are included under EP 12.1 (also within MDR GSPR 17.4 and IVDR GSPR 16.4)</i></p>

## Proposal 12: AUS Essential Principle 13.4(3) Item 29 – For IVDs

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
<p><b>EP 13.4 (3) Instructions for the use of a medical device must include information mentioned in the following table that is applicable to the device.</b></p> <p><b>EP 13.4(3) Item 29</b> For an IVD medical device, information (including, to the extent practicable, drawings, and diagrams) about the following:</p>	<p><b>GSPR 20.4 Information in the instructions for use</b></p> <p><b>GSPR 20.4.1</b> The instructions for use shall contain all of the following particulars:</p> <p><i>Requirements of IVDR GSPR 20.4.1 (a) and (b) are included under AUS EP 13.4(3) Item 1 and Item 6, respectively.</i></p>	No proposed changes.
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p><i>Intended purpose is broadly covered under EP 13.4(3)2.</i></p> <p><b>No equivalent details within EP 13.4(3)29.</b></p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(c) The devices intended purpose:</p> <p>(i) what is detected and/or measured;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Details for the intended purpose for IVD devices are to include: <ul style="list-style-type: none"> <li>– (i) what is detected and/or measured;</li> </ul> </li> </ul>

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
	<p>(ii) its function (e.g. Screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);</p> <p>(iii) the specific information that is intended to be provided in the context of:</p> <ul style="list-style-type: none"> <li>— a physiological or pathological state;</li> <li>— congenital physical or mental impairments;</li> <li>— the predisposition to a medical condition or a disease;</li> <li>— the determination of the safety and compatibility with potential recipients;</li> <li>— the prediction of treatment response or reactions;</li> <li>— the definition or monitoring of therapeutic measures;</li> </ul> <p>(iv) whether it is automated or not;</p> <p>(v) whether it is qualitative, semi-quantitative or quantitative;</p> <p>(vi) the type of specimen(s) required;</p> <p>(vii) where applicable, the testing population; and</p> <p>(viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.</p>	<p>– (ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);</p> <p>– (iii) the specific information that is intended to be provided in the context of:</p> <ul style="list-style-type: none"> <li>▪ a physiological or pathological state;</li> <li>▪ congenital physical or mental impairments;</li> <li>▪ the predisposition to a medical condition or a disease;</li> <li>▪ the determination of the safety and compatibility with potential recipients;</li> <li>▪ the prediction of treatment response or reactions;</li> <li>▪ the definition or monitoring of therapeutic measures;</li> </ul> <p>– (iv) whether it is automated or not;</p> <p>– (v) whether it is qualitative, semi-quantitative or quantitative;</p> <p>– (vi) the type of specimen(s) required;</p> <p>– (vii) where applicable, the testing population; and</p> <p>– (viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.</p>

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(a) The scientific principle (the ‘test principle’) on which the performance of the IVD medical device relies;</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(f) the test principle;</p>	<p>No changes proposed.</p>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(b) Specimen type, collection, handling and preparation</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(q) conditions for collection, handling, and preparation of the specimen;</p>	<p>No changes proposed.</p>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(c) Reagent description and any limitations (for example, use with a dedicated instrument only);</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(h) a description of the reagents and any limitation upon their use (e.g. Suitable for a dedicated instrument only) and ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Include ingredient(s) of the reagents(s) or kit.</li> </ul>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(d) Assay procedure including calculations and interpretation of results;</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;</p> <p>(y) the mathematical approach upon which the calculation of the analytical result is made;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Where relevant, if any confirmatory testing shall be considered.</li> <li>• Where relevant, information regarding batch-to-batch variation provided with relevant figures and units of measure.</li> <li>• Calculations are to include the mathematical approach upon which the calculation of the analytical result is made.</li> </ul>

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(e) Interfering substances and their effect on the performance of the assay;</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(ab) information on interfering substances or limitations (e.g. Visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Include information on limitations that may affect the performance of the device, with examples for clarity.</li> </ul>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(f) Analytical performance characteristics, such as sensitivity, specificity, accuracy and precision;</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(w) analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user</p>	<p><b>Proposal 12(a)</b></p> <ul style="list-style-type: none"> <li>• Clarify requirements for analytical performance by including equivalent detail and examples, such as but not limited to, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user.</li> </ul>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(g) Clinical performance characteristics, such as sensitivity and specificity</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(x) clinical performance characteristics as defined in Section 9.1 of this Annex;</p> <p>(z) where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;</p> <p><i>For reference:</i></p> <p><i>IVDR GSPR 9.1. Devices shall be designed and manufactured in such a way that they are suitable for the</i></p>	<p><b>Proposal 12(a)</b></p> <ul style="list-style-type: none"> <li>• Clarify information required for clinical performance characteristic by including examples, such as, but not limited to: <ul style="list-style-type: none"> <li>– threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value.</li> <li>– diagnostic sensitivity, diagnostic specificity, likelihood ratio, expected values in normal and affected populations.</li> </ul> </li> </ul>

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
	<p><i>purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:</i></p> <p>(b) <i>the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.</i></p>	
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(h) Reference intervals, if appropriate</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(aa) where relevant, reference intervals in normal and affected populations;</p>	<p><b>Proposal 12(a)</b></p> <ul style="list-style-type: none"> <li>Clarify “reference intervals” by including “in normal and affected populations”.</li> </ul>
<p><b>EP 13.4(3) Item 29 continued.....</b></p> <p>(i) Any precautions to be taken in relation to substances or materials that present a risk of infection</p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(o) any warnings and/or precautions related to potentially infectious material that is included in the device;</p> <p>(ac) (i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;</p>	<p><b>Proposal 12(a)</b></p> <ul style="list-style-type: none"> <li>Include reference to risk of microbial hazards, such as, but not limited to, consumables contaminated with potentially infectious substances of human origin.</li> </ul>
<p><b>No equivalent AU Essential Principle.</b></p>	<p><b>GSPR 20.4.1 continued....</b></p> <p>(g) a description of the calibrators and controls and any limitation upon their use (e.g. Suitable for a dedicated instrument only);</p> <p>(i) a list of materials provided and a list of special materials required but not provided;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>Include a description of the calibrators and controls and any limitations upon their use.</li> <li>Include a list of materials provided and a list of special materials required but not provided.</li> </ul>

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
	<p>(l) in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;</p> <p>(t) where applicable, recommendations for quality control procedures;</p>	<ul style="list-style-type: none"> <li>• Include in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant.</li> <li>• Where applicable, include recommendations for quality control procedures.</li> </ul>
No equivalent AU Essential Principle.	<p><b>GSPR 20.4.1 continued....</b></p> <p>(u) the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Include the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;</li> </ul>
No equivalent AU Essential Principle.	<p><b>GSPR 20.4.1 continued....</b></p> <p>(ag) where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;</p>	<p><b>Proposal 12(a) NEW</b></p> <ul style="list-style-type: none"> <li>• Require any components within an IVD kit that are available as separate devices, must individually comply with the AUS Essential Principles.</li> </ul>
No equivalent AU Essential Principle.	<p><b>GSPR 20.4.2 In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:</b></p> <p>(a) Details of the test procedure shall be given, including any reagent preparation, specimen</p>	<p><b>Proposal 12(a) NEW</b></p> <p><b>For devices intended for self-testing:</b></p>



AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
	<p>collection and/or preparation and information on how to run the test and interpret the results;</p> <p>(b) Specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;</p> <p>(c) The device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;</p> <p>(d) The results shall be expressed and presented in a way that is readily understood by the intended user;</p> <p>(e) Information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;</p> <p>(f) The information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market</p>	<ul style="list-style-type: none"> <li>• The instructions for use must contain, <b>as a minimum</b>, the information below: <ul style="list-style-type: none"> <li>– (a) details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;</li> <li>– (b) specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;</li> <li>– (c) the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;</li> <li>– (d) the results shall be expressed and presented in a way that is readily understood by the intended user;</li> <li>– (e) information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;</li> <li>– (f) the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without</li> </ul> </li> </ul>

AUS Essential Principle 13.4(3)Item 29	EU IVDR	Proposal 12 - Intent and <i>comments</i>
	<p>on where a user can obtain further advice such as national helplines, websites;</p> <p>(g) For devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.</p>	<p>first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;</p> <p>– (g) for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.</p> <p><b>Proposal 12(b) AUS-specific</b></p> <ul style="list-style-type: none"> <li>• If specific particulars of EP 13.4(3)29 are omitted, as permitted under GSPR 20.4.2(b), the omitted information must be available and presented to the Secretary upon request according to the legislated timeframes for such requests.</li> </ul> <p><i>Where the GSPR refers to (EU) Member States, the Australian legislation will refer to the appropriate Australian department/s.</i></p>

## Version history

Version	Description of change	Author	Effective date
V1.0	Original document	Devices Reforms Taskforce	August 2024

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