Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Medical Device Essential Principles - Part 2: Proposed alignment with the EU Regulation

Consultation response summary

Version 1.0, November 2025

Copyright

Contents

Response summary

Proposal 1 - Develop new EPs based on EU MDR/IVDR GSPR 2, 3, 5, and EU MDR GSPR 22

Proposal 1 suggested adopting the intent of certain EU General Safety and Performance Requirements (GSPRs) that currently have no equivalent in the Australian Essential Principles. These new requirements focused on reducing risks, strengthening risk management systems, and ensuring protection for users and the general public.

Respondents generally supported aligning the Australian Essential Principles (AUS EPs) with the intent of EU MDR/IVDR GSPRs 2, 3, 5, and 22, noting that this would improve device safety and align with international standards.

However, many felt these requirements are already addressed in the current AUS EPs. They recommended using guidance document to clarify the intent and support alignment, rather than introducing new EPs. Creating new EPs could lead to duplication causing redundancy and increase regulatory burden on industry.

Proposal 2 - Amend AUS Essential Principles 2 & 4

Proposal 2 recommended targeted amendments to EP 2 and 4 to align with the corresponding GSPRs. These amendments focused on the design and construction of medical devices in accordance with established safety principles, with particular emphasis on ensuring long-term safety throughout the device lifecycle.

Overall, consultation respondents supported the proposal to align AUS EP2(d) with the intent of EU MDR GSPR 4(c) and AUS EP4(a) with the intent of GSPR6/IVDR GSPR 9. They agreed that these changes would support device safety but noted that current EPs already cover these requirements.

Stakeholders in favour of aligning EP2(d) said clearer warnings and precautions on device labels would help healthcare professionals use devices safely. Whereas those not in favour stated the proposed wording was too restrictive and less principles-based than the current EPs, potentially increasing regulatory burden for manufacturers.

While stakeholders supported the intent of aligning EP4(a), they raised concerns that the proposed wording could create unrealistic expectations for device performance over time. It might imply that normal wear and tear could make a device non-compliant. Those who disagreed argued that manufacturers already address wear and tear in their risk assessments to ensure safety. Industry stakeholders felt the proposal was less flexible than the EU MDR/IVDR wording and could be misinterpreted regarding how a device should perform throughout its lifetime.

Proposal 3 - Amend AUS Essential Principle 7

Proposal 3 recommended enhanced alignment with the intent of the GSPRs regarding chemical, physical, and biological properties. This included considerations for material interactions, particle leakage and leaching, as well as requirements related to ingress and egress.

Most respondents supported aligning AUS EP7 with relevant EU MDR and IVDR GSPRs, stating that this would improve device safety and support international harmonisation.

However, some concerns were raised regarding manufacturers inability to have the required data available during initial design and validation, leading to additional compliance costs that could be passed on to consumers and purchasers.

Stakeholders recommended:

- Further consultation to address industry concerns.
- Avoiding duplication of existing requirements.
- Managing regulatory impact through appropriate transition periods and alignment with conformity assessment procedures.

Hospitals, clinicians, and their peak bodies supported expanding EP7, saying it would:

- Improve clarity on material safety and compatibility.
- Enhance long-term patient safety by controlling leaching substances.
- Provide clearer guidance for devices with absorbable or locally dispersed substances.

Some Industry stakeholders felt compliance would be difficult for devices without CE marking registered via non-EU MDR pathways and Class I non-measuring, non-sterile devices. They cautioned against including detailed EU-style requirements in guidance documents, warning this could lead to 'scope creep' beyond what is supported by Australian regulations.

Proposal 4 - Amend AUS Essential Principle 8

Proposal 4 recommended improved alignment with the GSPRs concerning infection control and microbial contamination. This included considerations for in-vitro diagnostic (IVD) devices containing biological material of human origin that is non-viable or rendered non-viable, as well as non-IVD devices manufactured using biological material. Most respondents supported aligning AUS EP8 with relevant EU MDR and IVDR GSPRs, noting that the proposals reflect global best practices.

However, several stakeholders stated that the current EP8 already broadly covers the safety requirements. They recommended using guidance material to provide further clarification and examples, rather than changing the EP itself. A principles-based approach was preferred, allowing flexibility and avoiding additional labelling requirements, especially for small packaging, where implementation could be challenging.

Some stakeholders felt the proposals were too prescriptive and would place an unnecessary burden on manufacturers, particularly those outside the EU. They requested:

- Clarification on the scope - which devices the new requirements would apply to.
- A clear definition of terms, such as 'specific microbial state'.

Proposal 5 - Amend AUS Essential Principle 9

Proposal 5 suggested updating EP 9 to better align with GSPRs. These changes were related to the construction and environmental properties of medical devices, including how they are designed and manufactured.

Overall, consultation respondents were in favour of aligning EP9 with the intent of relevant MDR GSPR and IVDR GSPR, stating that the proposed changes will enhance device safety, especially in terms of compatibility, environmental risk management and ergonomic design whilst promoting global alignment. However, stakeholders emphasized the need to avoid redundancy or overlap with existing EPs and include qualifiers like 'where applicable' or 'where appropriate' to ensure requirements only apply when relevant.

Those who were not in favour felt the changes were too burdensome and could lead to over-regulation. They noted that 'ergonomic' design is not currently required under Australian regulations or ISO 14971 and that the devices not supplied in the EU may struggle to demonstrate compliance. Further consultation was recommended to ensure minimal impact on sponsors and manufacturers.

Proposal 6 - Amend AUS Essential Principle 11

Proposal 6 addressed requirements for protecting users from radiation, including updating terminology by replacing the terms ‘visible radiation’ and ‘invisible radiation’ with the more precise terms ‘non-ionising radiation’ and ‘ionising radiation’.

Most respondents supported aligning EP11 with relevant EU MDR and IVDR GSPRs, stating that the changes would:

- Improve clarity
- Maintain high standards in radiation safety and device performance
- Promote consistency with national and EU regulations through terms like ‘ionising’ and ‘non-ionising’
- Enhance visual and audible warnings for radiation-emitting devices
- Emphasize reproducibility of emission parameters, reassuring both patients and users

Those not in favour felt the changes are too onerous. It was stated that information on acceptance and performance testing, acceptance criteria and maintenance procedures is more relevant to a qualified technician and may not need to be included in the IFU unless directly related to device use. Clarification was requested on whether investigational devices would require ARPANSA radiation dosage assessment.

There was mixed feedback on the proposals listed under part (b), related to EP11 reiterating requirements from other EPs with most of the hospital/health professionals and their peak bodies in favour and medical device industry not in favour of the proposal.

Those in favour stated that reiterating requirements promotes a comprehensive device safety approach.

Those not in favour raised concerns about:

- Redundancy and duplication of existing requirements
- Limited benefit to consumers
- Increased complexity for manufacturers, who already assess EP applicability based on device characteristics

Stakeholders suggested to include references to relevant EPs in guidance documents for a more streamlined and flexible framework.

Proposal 7 - Amend AUS Essential Principle 12

Proposal 7 focused on updating EP 12 to align with GSPRs for medical devices that are connected to or powered by an energy source.

Overall, consultation respondents were in favour of aligning EP12 with the intent of relevant MDR GSPR and IVDR GSPR, stating that the proposals would

- Strengthen safety by requiring design measures to mitigate risks such as overheating, electromagnetic interference, and single-fault conditions
- Improve the safe operation of energy-dependent devices through reliable power supply and robust control mechanisms
- Enhance safety, reliability, and cybersecurity of programmable and assistive technologies

However, it was noted that some of the proposed new requirements are already covered by existing EPs such as EP 12.6, 12.11, 9.2, 7.3 and 12.12 and duplication will result in redundancy.

Those who were not in favour stated that the proposals are burdensome for Australian manufacturers and could result in over-regulation. Concerns were raised about Aus-specific requirements, noting that the goal of this consultation was to align with the EU framework. Concerns were also raised around the risk of non-compliance by non-CE marked devices. It was suggested to qualify requirements with ‘where relevant’ or ‘where feasible’ to avoid imposing mandatory obligations where

not applicable. Further guidance material was recommended to clarify expectations and provide examples.

Proposal 8 - Amend AUS Essential Principle 15

Proposal 8 recommended aligning EP 15 with the EU In-Vitro Diagnostic Regulation (IVDR) GSPRs. This included clarifying requirements for analytical and clinical performance and expanding certain provisions to cover devices intended for point-of-care (POC) testing."

Most respondents supported aligning EP15 with relevant EU MDR and IVDR GSPRs under proposal 8(a), stating that changes will help manufacturers understand the requirements and that the requirements will be better aligned with the EU resulting in global harmonisation. Further it was noted that the proposal to allow device performance to be maintained throughout its lifetime will reinforce long-term reliability, ensuring that devices continue to function accurately and safely over time.

Some of the stakeholders disagreed or partly agreed to these proposals highlighting the impact of adopting EU requirements on the use of approvals from other overseas regulators, which may not enforce similar requirements. Further adding that number of IVDs on the ARTG via MDSAP pathway have not transitioned to IVDR, making compliance with IVDR GSPRs difficult within the proposed transition period. Some stakeholders suggested the proposals to be more flexible as per below rationale:

- Calibrators and controls are not always metrologically traceable and may be set by consensus or user-defined standards,
- POC testing devices cannot feasibly be verified for all use scenarios
- IVDs often have short shelf lives, so the term 'lifetime' may be inappropriate

It was suggested that some of these requirements are better suited to be included in a guidance document.

There was mixed feedback regarding the Aus-specific proposal mentioned under 8(b), which recommended that all IVD medical devices incorporate provision enabling users to verify that the device performs as intended and receive a warning if the device fails to produce valid results. Of those who agreed, the majority were health professionals and their peak bodies stating that the AUS-specific enhancement ensures that all IVD devices include provisions for users to verify device performance at the time of use and receive warnings for invalid results, thereby improving reliability across a wider range of diagnostic contexts. Of those who disagreed, majority were industry representatives and peak bodies stating that proposal will lead to misalignment between TGA and IVDR GSPR requirements and could increase regulatory burden on the industry. It was suggested that the requirement should include qualifiers like 'where appropriate/applicable' as verification of IVD performance is not always possible, and that only the end user and their skills will determine if the test was performed as intended.

Proposal 9 - Amend AUS Essential Principle 13.1

Proposal 9 had a number of sub-proposals and suggested aligning our requirements for information provided with medical devices to match GSPRs. This included details on device performance, intended users, residual risks, and relevant hazard symbols for dangerous goods. Additional Australia-specific proposals included requirements on information in machine-readable formats, ensuring legibility through font size, type, and contrast, and providing instructions for use (IFU) for devices intended for laypersons.

Proposal 9a - Most respondents supported aligning EP13.1 with relevant EU MDR and IVDR GSPRs, stating that the proposed changes would improve the quality of information provided to users, crucial for effective and secure device operation, including:

- Specific performance indicators

- Safety instructions
- Residual risk information

It was further added that that mandating clear and accurate labelling and including comprehensive instructions for safe usage on dental devices will enhance the safety and efficacy of dental procedures. Feedback also suggested that the proposals will support accessibility by allowing information to be provided in audio, tactile, or digital formats for sight-impaired or blind users.

Stakeholders not in favour or partially in favour of the proposal stated that Aus-specific requirements, particularly related to labelling and information provided may increase regulatory and cost burden on the industry. Further adding that country-specific changes could create barriers to market entry for new products. On the need to provide an IFU with each device in multipack of devices, those not in favour stated that this will result in redundance, which is waste of resources and environmentally unfriendly, especially when it adds no clear value.

Proposal 9b - Most respondents who were in favour of aligning the intent of EU GSPR23.1(c) with EP13.1(3) stated that the information to be supplemented by machine readable formats that does not compromise device performance or ability to meet the Aus EPs is an efficient and forward-looking proposal. Those who disagreed stated that Aus-specific requirements must be avoided, or wording of proposal must allow flexibility by including qualifiers such as ‘where applicable or appropriate’

Proposal 9(c-d) - There was strong opposition from the medical device industry regarding the Aus-specific legibility requirements. Stakeholders opposing the proposed font changes stated that specifying font size and type is unnecessarily restrictive, difficult to enforce and will cause misalignment with the EU GSPR. It was noted that legibility of text can vary significantly between printed materials and digital displays. It was also noted that for medicine labelling AUST R and AUST L numbers are allowed by the TGA in 1mm font size indicating that for most people that legibility is acceptable. A font size that appears clear on a high-resolution screen may not be legible on a small printed label.

Stakeholders opposing the proposed incorporation of text contrast with background stated that solely focusing on text contrast is not sufficient for readability. Other factors, such as font size, style, and placement, also play a crucial role. Stakeholders further stated that the manufacturer determines appropriate legibility during risk analysis and product design and that the requirements should align with the international standards (EU MDR Article 10(11), ISO 15223-1, ISO 20417, relevant GSPR) that optimizes device safety and effectiveness without imposing additional regulatory burdens unique to Australia.

Supporters of Proposal 9(c) stated that moving from a 1mm minimum text height to a standardised font (e.g. 8pt Times New Roman) would improve readability across device interfaces and be especially beneficial for software and device displays. Those in favour of proposal 9(d) felt that emphasizing contrast for warnings, precautions, and contraindications is a practical enhancement that will improve visibility, particularly in software interfaces and on-screen displays. Stakeholders recommended that legibility considerations be addressed in a guidance document, rather than through prescriptive EP changes.

Proposal 9e - There was divided opinion on the proposal to require an IFU with every device intended for use by lay persons.

Stakeholders opposing the proposal agreed that clear and comprehensive instructions are essential for lay users, but providing one physical copy of the IFU with options for digital access and updates is a balanced approach that addresses environmental, cost, and user preference considerations. This Aus-specific requirement could lead to unnecessary packaging changes, potentially affecting product availability in Australia.

Stakeholders in favour highlighted the growing use of healthcare devices in non-clinical settings, such as home and telehealth environments. It was stated that the proposal will support safe and accurate use of devices including hardware or software used by non-professionals.

The feedback on changes mentioned under proposal 9 overall echoed the need for the TGA to be cognisant of adding Aus-specific requirements and recommended adopting internationally harmonised standards to reduce regulatory burden.

Proposal 10 - Amend AUS Essential Principle 13.3

Proposal 10 recommended aligning device labelling requirements with the relevant GSPRs. This included general labelling standards for information provided with the device, critical safety details, quantitative information on key components in combination products, indications of microbial status or cleanliness, inclusion of a Unique Device Identifier (UDI), and specific labelling requirements for packaging of devices supplied in sterile condition.

Overall, most consultation respondents were in favour of aligning EP13.3 with the intent of relevant MDR GSPR and IVDR GSPR however, stakeholders from medical device industry raised significant concerns related to new labelling requirements, questioning the need to introduce these changes and benefit to consumers. Most stakeholders representing medical professional and their peak bodies were in favour of these proposals, stating that the changes would improve clarity, consistency, and comprehensiveness of information provided with assistive technology devices.

Clear presentation of critical warnings, restrictions, and precautions on device labels, with detailed information in the IFU, was seen as a balanced approach to support safe and effective use. It was however noted that some devices e.g. in dental sector or biopsy markers, are extremely small and there is limitation on the amount of information that can be provided through labelling. Therefore, the clause referring to keeping critical information to minimum on labelling and detailed information be provided through IFU should be the determining factor where size of device impedes the ability to meet labelling requirements.

Feedback in favour of proposals related to providing essential identification details, such as the device name and the manufacturer's registered address (excluding PO boxes) highlighted that the requirements will

- Enhance label clarity for assistive technologies
- Facilitate efficient updates, recalls and cybersecurity measures for software and hardware medical devices
- Improve traceability through inclusion of:
  - Device name
  - Manufacturer’s registered address (excluding PO boxes)
  - UDI for non-IVD devices, supporting updates, recalls, and cybersecurity

It was further suggested that alternative formats and digital supplementation should be considered so that consumers who are sight-impaired or blind can access necessary device related information.

The stakeholders that were not in favour of the proposals stated that the EU specific labelling requirements will result in significant compliance barrier for products that are approved by other overseas comparable regulators (e.g. non-CE marked). In addition, any extra text in shared labelling/IFU with Europe will also require to be translated into 20+ languages which is a significant undertaking.

It was also highlighted that some of these requirements are not applicable for certain devices, for e.g.

- Quantitative information of the main constituent responsible for achieving the principal intended action where the device action cannot be attributed to specific ingredients
- UDI is not required for Class I devices, making the proposal inapplicable in some cases
- Font size requirements may limit the amount of information that can be included

Stakeholders recommended:

- Avoiding Aus-specific labelling requirements outside those proposed under EU MDR/IVDR
- Using a guidance document to outline labelling expectations

- Adopting a flexible approach similar to prescription and nonprescription medicines (TGO 91, 92), allowing variation in how manufacturer contact details are presented

Proposal 11 - Amend AUS Essential Principle 13.4(3)

Proposal 11 recommended aligning requirements for medical device IFU with the relevant GSPRs. This included considering on providing key information such as indications for use, expected clinical benefits, and other essential details to support safe and effective use.

Although, consultation respondents were in favour of aligning EP13.4(3) with the intent of relevant MDR GSPR and IVDR GSPR, the feedback reflected a broad range of views across industry and non-industry stakeholders. The non-industry stakeholders acknowledged the potential benefits of improved clarity, safety, and international harmonisation; the industry stakeholders raised concerns about the practicality, enforceability, and relevance of certain EU-specific requirements.

Stakeholders in favour stated that the proposals enhance risk mitigation by requiring comprehensive instructions related to contact information, warnings, emergency protocols and contraindications in specific for single use devices, implantable devices and devices used in dental practice. Including details like device name, intended use, residual risks, and compatibility improves user understanding of device operation and limitations.

The granularity of information proposed to be provided with IVD devices gives users the essential insights into device functionality, whilst fostering informed and accurate usage.

Stakeholders suggested to

- Include qualifiers like ‘where applicable’ to maintain flexibility
- Consider alternative formats (such as Braille, audio, and large-print), multilingual instructions, and digital solutions of IFU for NDIS participants,
- Use guidance documents to provide examples, avoiding unintended mandatory requirements

Stakeholders not in favour stated that EU-specific requirements may create regulatory barriers for non-EU approved products, limiting market access. While alignment is feasible for CE-marked devices, some requirements (e.g. GSPR 23, Summary of Safety and Clinical Performance) may not be met by devices approved via FDA, Health Canada, or Japan to support a device application.

The proposal to include known restrictions on device combinations was seen as onerous give the possibilities related to how devices and equipment interacts are too variable to identify and document.

Concerns about requiring manufacturer contact details and technical assistance numbers on labels or IFUs for professional-use devices:

- Considered irrelevant to end users
- Could cause confusion and increase compliance costs

It was further stated that whilst TGA’s intentions behind aligning the EPs is understandable, some of the requirements may not be applicable to all the intended devices therefore use of words such as ‘were applicable’ was suggested to maintain flexibility. Stakeholders stated that the TGA should further consultation with the relevant stakeholders before making these changes so the regulatory burden can be minimised.

Proposal 12 - Amend AUS Essential Principle 13.4(3)29

Proposal 12 suggested aligning the requirements for IFU for in vitro diagnostic (IVD) devices with the EU IVDR standards. This included specifying the intended purpose of the device, listing reagent or kit ingredients, outlining limitations that affect performance, providing analytical and clinical performance information, clarifying reference intervals by including both normal and affected populations, and defining minimum information for self-testing devices.

There was broad support for harmonisation with the EU standards, however, stakeholders raised concerns about the applicability of certain GSPR elements across all IVD types, the inclusion of proprietary information, and the need for flexibility in implementation.

Those stakeholders in favour of the proposals stated that the proposals will enhance clarity on the purpose of the IVD device and its use through provision of comprehensive information on performance and limitations. Further adding that the proposal for self-testing IVD devices will improve user safety and result interpretation through provision of clear instructions for use, actions needed for different result types, and cautionary statements for users to consult healthcare professionals before making any medical decisions based on test results.

Stakeholders opposing the proposals stated that if information is not explicitly needed for IVDR certification, it may not be readily available in the format that TGA would request. Therefore, consideration should be given to transition timeframes, so manufacturers are able to comply with these specific requirements. Further it was suggested that some proposed content under 'intended purpose' may be better placed under warnings, precautions, or contraindications.

Stakeholders in favour of the Aus-specific proposal on 'omitted information to be readily available and provided to the Secretary upon request' stated that the provision reinforces transparency and ensures that comprehensive device information is accessible to regulatory authorities, when necessary, whilst supporting effective oversight.

Those not in favour cautioned the TGA that:

- Aus-specific requirements could diverge from current EPs and EU standards.
- The TGA should assess whether these changes truly benefit consumers.
- New requirements may increase regulatory, resource and cost burden on the industry, especially for smaller companies.
- It could be difficult for manufacturers operating in multiple markets.

One of the stakeholders added that GSPR 20.4.2(b) is specific for self-testing and the information omitted is most likely due to the complex nature of the functionality that is not necessary for the lay person to understand the test procedure. This should not be used as a 'catch all' for all IVD devices or to audit all missing information which may or may not be applicable for that self-test.

Proposal 13 - Amend AUS Essential Principle 13B

Proposal 13 recommended clarifying EP 13B regarding software requirements, including specifying that the current build number of the software must be provided.

Most stakeholders supported the clarification, agreeing it provides necessary flexibility and avoids unnecessary regulatory burden.

Stakeholders in favour of proposal requiring software version and build numbers only when relevant to safety, maintenance, or user functionality stated that it aligns with the principle of providing transparency and safety without overburdening users with technical details. It was noted that for most users, the version number is sufficient to track and support software updates, a build number are mainly for internal use and don't help users unless they're part of version tracking.

Stakeholders not in favour stated that the proposal does not align with any of the EU MDR GSPRs and is also not a requirement for other comparable overseas regulators, thus will be difficult for manufacturers to comply to the Aus-specific requirement. The feedback reflects a consensus that traceability can be effectively maintained through more streamlined and existing identifiers such as serial or version numbers, without imposing additional complexity on users or manufacturers.

Some stakeholders questioned the scope and applicability of EP13B stating that the requirements only make sense for stand-alone software such as SaMD as opposed to devices incorporating software such as firmware where the software is not able to be updated once the device is supplied.

Proposal 14 - Amend Regulation10.2

Proposal 14 suggested updating Regulation 10.2 to clarify the information that sponsors must provide. Specifically, for IVD devices, this proposal required Australian sponsors to ensure that an appropriate level of technical support is available to customers in Australia.

The non-industry stakeholders supported the proposal saying it could improve customer support and align with EU IVDR, however, there was strong disagreement from industry stakeholder. There were concerns raised about enforceability, relevance to professional-use IVDs v/s self-testing IVDs, and the risk of creating barriers for international manufacturers. The feedback was in favour of ensuring technical support is available but preferred a risk-based and flexible approach that recognizes existing commercial practices, avoids adding Australia-specific requirements.

It was suggested that the proposed requirements need to be considered as per implementation of UDI database and that sponsor details can be provided through the database therefore removing the requirements of this information to be supplied with the device.

Stakeholders highlighted current industry practice wherein for IVD devices (all, point of care, self-testing), the point of contact remains as the Australian sponsor and that a user should not be calling an international entity.

Furthermore, following concerns were raised:

- Enforcing written agreements with overseas manufacturers may be difficult.
- Overseas support lines may need to be in English and available in Australian time zones, which could be costly.
- Verbal support (e.g., phone calls) may not be reliable if staff aren't well-trained or users misunderstand instructions, leading to incorrect device use.

Proposal 15 - Adopting Definitions

Proposal 15 recommended aligning certain definitions with those used in EU regulations to improve clarity and consistency. This included introducing definitions for 'interoperability' and 'benefit-risk determination,' and amending the definition of 'lay person' so that it applies to all medical devices.

Overall, stakeholders were in favour of aligning the definitions stating that internationally harmonised and accepted definitions will enhance device safety, usability, and effectiveness. Further adding that definitions of

- 'interoperability' will ensure seamless device integration
- 'Benefit-Risk Determination' will support consistent assessments of safety and performance, essential for regulatory evaluation and risk management across the industry, and
- expanding the 'lay person' definition will improve usability and safety for non-professional users of a wide range of medical devices.

Those stakeholders not in favour of adopting proposed definitions stated that the internationally harmonised and accepted definitions should be used, and if not available, then the EU definitions should be used instead.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Device Reforms Taskforce	November 2025

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au

Reference/Publication #