



Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Proposed medical device classification for human cells, tissues and organs storage solutions and IVF media

March 2019

TGA Health Safety
Regulation

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Introduction

The Australian Government endorsed a significant program of reform to further strengthen the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

In 2015, the Report of the *Expert Panel Review of Medicines and Medical Devices Regulation* (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The [Australian Government Response to the Review of Medicines and Medical Devices Regulation](#) was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty¹ which addressed matters within the remit of the TGA. This Recommendation provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure our assessments and decisions are made based on the balance between the benefits and the risks.

The risk classifications of medical devices take into account factors such as potential harm, level of invasiveness, reliance on power, where in the human body the device is used, terms of use, the end user (consumers or a person with appropriate knowledge and expertise), etc.

The TGA periodically reviews classification rules for medical devices to ensure they continue to be appropriate. When undertaking such assessments, the TGA has regard, among other things, to the international best regulatory practice and any emerging issues.

This ensures sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, and timeliness of access to medical devices.

This consultation

The focus of this paper is to obtain feedback on a proposal to introduce a new classification rule for non-invasive medical devices consisting of a substance, or a mixture of substances, intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body; or with human embryos, before their implantation or administration into the body.

This paper will also focus on some other clarifications to the existing rules in Part 2, Schedule 2 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

¹ Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, p. 10.

The [EU Regulation on medical devices \(2017/745\)](#)² (EU MD Regulation) introduced several amendments to the classification rules effectively reclassifying some categories of medical devices to higher risk classes.

The EU MD Regulation explains that the new requirements increase the robustness of the assessment process, and that the classification rules take into account the potential risks associated with the technical design and manufacture of the devices. The rules also take into account the level of invasiveness and potential toxicity of certain devices introduced into the human body as well as the place where the device performs its action in or on the human body.

The Australian Government's reforms aim to improve the scope, clarity and appropriateness and operation of regulations governing medical devices. This consultation paper considers the EU regulatory framework as an input into the review and reform of the Australian regulatory requirements for medical devices classification. While the new classification rule in the EU more appropriately reflects the intended use and the risk of medical devices, this paper considers the extent to which a similar approach will be appropriate in the Australian regulatory context, to further our aim of enhancing the smooth functioning of the medical devices market while also achieving high standards of quality, safety and performance.

Proposed changes: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, consider introducing a new classification rule, which is appropriately tailored for the Australian regulatory context, for non-invasive medical devices that are substances intended to be used, in particular, as human cells, tissues, organ storage solutions and *in vitro* fertilisation (IVF) media.

In the EU MD Regulation these are referred to as: ***"All non-invasive devices **consisting of a substance or a mixture of substances** intended to be used in vitro in **direct contact with human cells, tissues or organs taken from the human body** or used in vitro **with human embryos before their implantation or administration into the body.**"***

Also to propose a number of amendments to clarify the existing classification rules for some non-invasive medical devices.

Proposals

It is proposed that a **new classification rule** be included in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (Australian MD Regulations), to align with Rule 3 of the EU MD Regulation.

It is also proposed to incorporate a **number of clarifying amendments** into existing classification rules 2.2 and 2.3 in Schedule 2 of the Australian MD Regulations to ensure clarity of the regulatory requirements for non-invasive medical devices covered under these rules (see [Appendix A – Classification Rules](#)).

² The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Effect

Classification of non-invasive medical devices that are substances or a mixture of substances intended to be used in vitro, in direct contact with human cells, tissues, organs or with human embryos before implantation/administration, will be **Class III (high-risk) medical devices**.

Further the amendments to classification rules 2.2 and 2.3 of the Australian MD Regulations will provide greater clarity of the regulatory requirements. There will be no change to the classification of the devices specified in classification rules 2.2 and 2.3.

Your feedback

Are you a consumer, industry stakeholder, healthcare provider, patient, industry representative body, consumer advocacy group or other interested party?

We seek your views on the proposed amendments and implementation strategy. Your input will assist us to address any unintended consequences and inform the proposal and the regulatory amendment process.

On page 15 is a [list of questions](#) to help you address the proposal in your feedback.

Please refer to page 15 on [How to submit](#) your feedback to the TGA.



Please note

This consultation closes on **29 April 2019**.

Before providing feedback, it is important to read the explanatory material that follows.

Where do I find the medical device classification for human cells, tissues and organs storage solutions and IVF media?

EU

Regulation (EU) 2017/745 (the EU MD Regulation) specifies the rules that govern the classification of a medical device.

Rules 3 and 2³ prescribes the classification of particular groups of non-invasive medical devices.

³ [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices, Annex VIII, Chapter III – Classification Rules, 4.2 Rule 2 and 4.3 Rule 3 (OJ L 117, 5.5.2017, p. 141). See also Chapter V, Section 1, Article 51.1 – Classification of Devices, (OJ L 117, 5.5.2017, p. 49).

The second paragraph of Rule 3 relates to medical devices that are substances used as human cells, tissues and organs storage solutions and/or IVF media:

4.3. - Rule 3

(second paragraph)

*All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in **direct contact with human cells, tissues or organs taken from the human body** or used in vitro with **human embryos** before their implantation or administration into the body are classified as **class III**.*

Rule 2 and the first paragraph of Rule 3 of the EU MD Regulation provides the classification of other non-invasive medical devices used with blood, body liquids, cells or tissues, and liquids or gases.

4.2. - Rule 2

*All non-invasive devices intended for **channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body** are classified as **class IIa**:*

- *if they may be connected to a class IIa, class IIb or class III active device; or*
- *if they are intended for use for channelling or storing blood or other body liquids or for **storing organs, parts of organs or body cells and tissues**, except for blood bags; blood bags are classified as class IIb.*

In all other cases, such devices are classified as class I.

4.3. - Rule 3

(first paragraph)

*All non-invasive devices intended for **modifying the biological or chemical composition of human tissues or cells**, blood, other body liquids or other liquids **intended for implantation or administration into the body** are classified as **class IIb**, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.*

Some terminology used in relation to these Rules, including the term *invasive device*, is defined in the EU MD Regulation. The TGA is consulting on the possible alignment of this definition separately.⁴

Australia

The classification rules for medical devices in Australia are prescribed in Schedule 2 of the Australian MD Regulations.⁵

⁴ [Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia](#), Appendix A, Table A2, p.16

⁵ Classification rules for IVD medical devices are prescribed in Schedule 2A; see also [Therapeutic Goods Act 1989](#), s. 41DB and [Therapeutic Goods \(Medical Devices\) Regulations 2002](#), Part 3, Div. 3.1.

Rules 2.2 and 2.3 of Schedule 2 of the Australian MD Regulations correlate with the classification of Rule 2 and the first paragraph of Rule 3 of the EU MD Regulation. Both the Australian MD Regulations and the EU MD Regulation, cover similar groups of medical devices, however there are some drafting differences that may require clarification to improve the understanding of the regulatory requirements in Australia.

It is proposed to harmonise drafting of the Australian classification rules 2.2 and 2.3 with Rule 2 and the first paragraph of Rule 3 in the EU MD Regulation to improve clarity and consistency and enhance the smooth functioning of the medical devices market while also achieving timely access and high standards of quality, safety and performance. There will be no changes to the classification of these devices.

The Australian MD Regulations do not currently have rules equivalent to the second paragraph of EU MD Regulation Rule 3 related to non-invasive medical devices used as human cells, tissues, organs storage solutions and IVF media.

The current classification rules relevant to medical devices within the scope of the EU Rules 2 and 3 and principles for applying these rules under the Australian MD Regulations are outlined in [Current classification of these devices in Australia](#) (see page 11 of this paper).

[Appendix A – Classification rules](#) (on page 16) has been included as a reference tool. It provides a comparison of classification rules applicable to non-invasive medical devices in the EU MD Regulation and Australian MD Regulations.

Appendix A may help you in providing your feedback.

Medical devices subject to the 2nd paragraph of EU MD Regulation Rule 3

The second paragraph of EU MD Regulation Rule 3 classifies non-invasive medical devices consisting of a substance, or a mixture of substances, intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or with human embryos, before their implantation or administration into the body.

What are IVF media medical devices?

In vitro fertilisation (IVF) is a procedure used to overcome a range of fertility issues, by which an egg and sperm are joined together outside the body, in a specialised laboratory. The fertilised egg (embryo) is placed in a culture medium (nutritive liquid) and is allowed to grow in a protected environment for some days before being transferred into the woman's uterus. This process increases the chance of a pregnancy occurring.

Devices consisting of a substance, or a mixture of substances, intended to be used *in vitro* with human embryos (known as IVF culture media) were developed to mimic the composition of oviduct and uterine fluids to closely simulate the natural environment of the developing embryo. Commercial IVF culture media contain salts, growth factors, and/or other reagents such as trace elements, nuclease inhibitors, etc.

The quality of IVF culture media is important for the IVF outcomes. It may have an impact on pre and post-implantation development and possibly the future health of the child.

What are substances used *in vitro* in direct contact with human cells, tissues and organs?

There are several groups of non-invasive medical devices that are substances or mixture of substances used *in vitro* in direct contact with human cells, tissues and organs, including:

- Solutions used for hypothermic flushing, transport, and storage of organs for transplant. These solutions are intended to maintain organ viability until the organ can be implanted.
- Materials intended to maintain the viability of the corneal tissue used for storage and transport of harvested corneas prior to transplantation to the recipient.
- Culture media used for *in vitro* cultivated from cells of human and animal origin, intended to cover skin wounds typically resulting from a burn injury.
- A blood preservation fluid used during the collection and storage of blood and blood components in a healthcare and/or a blood bank facility (typically in a laboratory associated with the collection of blood or during apheresis procedures that result in the collection of blood), to help maintain protein and blood cell viability during the freezing of blood. It is typically glycerol-based and is supplied in a container (e.g. a polypropylene bag). It is not intended for direct intravenous infusion.
- Sterile, ready-to-use solution with an electrolyte composition similar to that of blood (i.e. a dialysate) intended to exchange solutes with blood across a semi-permeable membrane. It is used within a haemodialysis system to remove metabolic wastes from the blood and to help maintain physiological blood electrolyte and pH levels. The product typically includes glucose and salts of the following constituents: sodium, potassium, magnesium, calcium, chloride, and anions of weak acids (e.g. bicarbonate (HCO_3^-), acetate, citrate and lactate).
- There are numerous organ storage solutions, with many new solutions currently in development. Some novel solutions act to maintain membrane polarity by allowing higher levels of high-energy phosphates to be generated through the glycolytic pathway during preservation, and mitigates the consequences of ischemia reperfusion injury overall. They have been developed to meet the energy requirements of cardiomyocytes and coronary endothelium, in addition to priming the organ with substrates and metabolites during storage to facilitate resumption of biochemical, physiological, and mechanical work upon post-transplantation reperfusion.

Further examples are provided in [Appendix B](#) - Examples (page 18).

Why reclassify non-invasive medical devices that are substances or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues, organs or with embryos?

Quality culture medium is essential for optimum patient outcomes. The advances in IVF around the world have been rapid and the use of IVF culture media is essential in this process. The market of IVF culture media has been expanding with examples including freezing media, biopsy media, etc., which can contain various components including nutrients, vitamins and growth factors.

Some research suggests that suboptimal culture conditions could cause long-term impacts on reprogramming in the embryo. The peri-conception period is particularly susceptible to epigenetic alterations.⁶

Further, there have been many changes and advancements in organ preservation solutions and this may potentially provide further challenges and opportunities to improve organ preservation solutions in the future.⁷

Therefore, the quality of media use *in vitro* should be monitored closely to help mitigate their potential risks.

Reclassifying non-invasive medical devices such as IVF media and substances used for storing human cells, tissues or organs to high-risk (Class III) devices will ensure an increased robustness of the assessment process and consequently minimise the potential risks associated with these medical devices not performing as intended.

Current classification applicable to these medical devices in Australia

There are currently no specific definitions and/or classification rules related to medical devices that are substances or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body.

The classification rules that apply currently to these devices are set out in Schedule 2, Parts 2 and 5 of the Australian MD Regulations as follows:

Rule 2.2 - Non-invasive medical devices intended to channel or store blood, etc.

(1) This clause applies to:

a non-invasive medical device that is intended by the manufacturer to be used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient; and

a non-invasive medical device that is intended by the manufacturer to be used to store an organ, part of an organ or body tissue that is to be later introduced into a patient; and

a non-invasive medical device that:

- i. is intended by the manufacturer to be used to channel or store a liquid or gas that is to be infused, administered or introduced into a patient; and
- ii. may be connected to an active medical device classified as Class IIa or higher.

(2) The device is classified as Class IIa.

⁶ Elpiniki Chronopoulou, Joyce C. Harper; IVF culture media: past, present and future, *Human Reproduction Update*, Volume 21, Issue 1, 1 January 2015, Pages 39–55, <https://doi.org/10.1093/humupd/dmu040>.

⁷ Guibert EE, Petrenko AY, Balaban CL, Somov AY, Rodriguez JV, Fuller BJ. Organ Preservation: Current Concepts and New Strategies for the Next Decade. *Transfus Med Hemother*. 2011;38(2):125-142.

Rule 2.3 - Non-invasive medical devices intended to modify the biological or chemical composition of blood, etc.

- (1) Subject to subclause (2), a non-invasive medical device that is intended by the manufacturer to be used to modify the biological or chemical composition of blood, other body liquids, or other liquids intended to be infused into a patient, is classified as Class IIb.
- (2) If the treatment for which the device is designed consists of filtration, centrifugation or exchanges of gas or heat, the device is classified as Class IIa.

Note: If a medical device used *in vitro* in direct contact with human cells, tissues or organs or human embryos contains a medicine, or animal or microbial or recombinant tissues, cells or other substances, such device will be already classified as Class III device in accordance with Rules 5.1 and 5.5 of Schedule 2 of the Australian MD Regulations.

Proposed reclassification

If the proposed reclassification takes effect, any non-invasive medical device consisting of a substance or a mixture of substances used *in vitro* in direct contact with human cells, tissues or organs or with embryos (such as solutions used for storing human cells, tissues and organs or IVF culture media) will be reclassified to Class III.

Sponsors of Class III medical devices in Australia are required to include each device in the [Australian Register of Therapeutic Goods](#) (ARTG) separately, with an individual unique product identifier (UPI) to improve their traceability. Medical devices of the high risk classification require the most stringent assessment of manufacturer's quality management systems and assessment of technical documentation related to each device, rather than that of a representative device from a group of similar devices.⁸ Sponsors will be required to obtain manufacturer's *conformity assessment documents*⁹ and provide them to the TGA to demonstrate procedures appropriate for a Class III medical device when submitting applications for inclusion of their medical devices in the ARTG. Finally the Class III device applications are also subject to a mandatory audit assessment by the TGA, including assessment of the clinical evidence.

Strengthened assessments are intended to drive the manufacture of better quality, reliable medical devices that are fit for purpose.

Proposed action

It is proposed that a **new classification rule** be included in Part 2 (Rules for non-invasive medical devices), Schedule 2 in the Australian MD Regulations, to align with the second paragraph in the EU MD Regulation Rule 3:

'All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as Class III.'

⁸ [Therapeutic Goods \(Medical Devices\) Regulations 2002](#), r.3.6 and Schedule 3 – Conformity assessment procedures

⁹ [Therapeutic Goods Act 1989](#), s.3

What will change for sponsors?

Sponsors who supply, or plan to supply, in Australia medical devices to which the second paragraph of EU MD Regulation Rule 3 applies will be required to provide manufacturer's *conformity assessment documents* appropriate to devices of this classification.¹⁰

If the regulatory changes take effect, sponsors of medical devices to which the second paragraph of EU MD Regulation Rule 3 applies, will be required to apply for inclusion of their medical devices in the ARTG as Class III.

Transitional arrangements

In Europe, under the transitional arrangements, medical devices lawfully placed on the market that have pre-market authorisation in the form of a valid EC Certificate¹¹ can remain on the market until the expiry date of that EC Certificate or until 27 May 2024 (when these certificates become void), whichever is the earliest. Devices lawfully placed on the market may continue to be made available on the market or put into service until 27 May 2025.

The TGA proposes that the new classification for **new medical devices in Australia**—that is, a device included in the ARTG following successful completion of applications submitted to the TGA on or after the commencement date of the amended regulations—would start from August 2020.

If the application for ARTG inclusion for a medical device is **submitted to the TGA before the date the proposed amendment takes effect**, it is proposed that the medical device will be subject to the transitional arrangements and will have four (4) years to transition until August 2024.

Applications

At the date that the proposed amendment takes effect:

- **All new applications for marketing approval** (ARTG inclusion) for these devices, submitted to the TGA on or after the date when amendments to the regulations take effect must be made for a Class III medical device.
- **Sponsors of devices already included in the ARTG**, or those for which applications have been submitted before regulatory amendments take effect, must apply to have their device/s re-entered as Class III medical devices. All applications to reclassify devices must be submitted to the TGA by the end of the four year transition period. Where an application to reclassify has been submitted to the TGA but has not been determined (i.e. is still under assessment), the device can continue to be supplied under the existing ARTG entry until the Class III application is finalised (including applications not finalised at the end of the transition period).
- For those **devices for which transitional provisions apply**, sponsors must notify the TGA of all such devices being supplied under the existing ARTG entry within six (6) months of the amended regulations taking effect (i.e. by February 2021). These devices can continue to be supplied for the duration of the four year transition period. If the sponsor has not notified the TGA within this period, they will no longer be eligible for the transitional arrangements.

¹⁰ [Therapeutic Goods \(Medical Devices—Information that Must Accompany Application for Inclusion\) Determination 2018](https://www.legislation.gov.au/Details/F2018L01410) (F2018L01410) <<https://www.legislation.gov.au/Details/F2018L01410>>

¹¹ EC certificates issued in accordance with EU Directive 93/42/EEC and which comply with the requirements in para. (2) of Article 120 of the EU MD Regulation.

TGA will follow a due process regarding making decisions on whether to cancel respective ARTG entries.

- If any **application for ARTG inclusion for a device with the current classification is in progress** on the date the regulations come into effect, it may continue. If the application is successful, the device will be included with the current classification. The sponsor must then reapply to include their device in ARTG as Class III, as per requirements set out under the transitional arrangements.

Fees and charges

The usual **application and audit assessment fees** will apply for applications for inclusion in the ARTG.

The usual annual charges will apply for Class III entries in the ARTG following reclassification.

Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal; and
- provide relevant material on the TGA website.

Feedback notes

It is important to note that while we intend to take the European medical device framework into account the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. We acknowledge that legislation cannot always be successfully replicated across jurisdictions. Therefore, your views on the impacts of reclassifying these non-invasive medical devices consisting of a substance or a mixture of substances used *in vitro* in direct contact with human cells, tissues or organs, or embryos to Class III are very important to us.

When considering the proposed measures, assume that the EU MD Regulation definitions and terminology and the second paragraph of Rule 3 apply to non-invasive medical devices consisting of a substance or a mixture of substances used *in vitro* in direct contact with human cells, tissues, organs, or embryos in the context of the Australian MD Regulations. You also may wish to consider the possible impact of the proposed alignment by referring to descriptions of relevant devices and their functionality.

Please also keep in mind that current and future technological developments may potentially bring more categories of medical devices under this classification rule.

What we invite you to do

In your submission, we ask you to consider the questions below and provide comments related to any other matter outlined in this consultation paper.



Questions

- What impacts—including any that are unintended—do you anticipate the proposed reclassification and clarification of classification rules may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?
- Are there any further issues and questions we should consider when implementing these changes (including areas that can/should be clarified in our guidance)?
- Is the proposed new classification for IVF media and medical devices that are substances used for storing human cells, tissues and organs to Class III appropriate?
- What groups of devices do you consider fall within the scope of the proposed change?
- What questions should we consider when clarifying amendments to classification rules 2.2 and 2.3?
- Do you have any comments regarding the transitional arrangements proposed in this paper?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, please ensure your submission is accompanied by a coversheet.

This consultation closes on 29 April 2019.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

Appendix A - Classification rules

There are a number of differences between the respective classification rules in the Regulation (EU) 2017/745 and the *Therapeutic Goods (Medical Devices) Regulations 2002*. The table below provides overview of provisions and its comparison.

EU MD Regulation	Australian MD Regulations	Proposed amendments
ANNEX VIII - CLASSIFICATION RULES Chapter III - Classification Rules	Schedule 2 - Classification rules for medical devices other than IVD medical devices Part 2 - Rules for non-invasive medical devices	
<p>4.2 - Rule 2</p> <p>All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:</p> <ul style="list-style-type: none"> if they may be connected to a class IIa, class IIb or class III active device; or if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb. <p>In all other cases such devices are classified as class I.</p>	<p>2.2 - Non-invasive medical devices intended to channel or store blood, etc.</p> <p>(1) This clause applies to:</p> <ul style="list-style-type: none"> (a) a non-invasive medical device that is intended by the manufacturer to be used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient; and (b) a non-invasive medical device that is intended by the manufacturer to be used to store an organ, part of an organ or body tissue that is to be later introduced into a patient; and (c) a non-invasive medical device that: <ul style="list-style-type: none"> i. is intended by the manufacturer to be used to channel or store a liquid or gas that is to be infused, administered or introduced into a patient; and ii. may be connected to an active medical device classified as Class IIa or higher. <p>(2) The device is classified as Class IIa.</p>	<p>It is proposed to consider whether some drafting differences should be clarified.</p> <p>EU MD Regulation Rule 2 applies among other things to non-invasive devices intended for channelling or storing cells or tissues. The respective part of the Australian rule does not specifically refer to cells or tissues.</p> <p>For this reason, the TGA proposes to amend our classification rule to improve clarity and understanding of the regulatory requirements, to facilitate better regulatory compliance and consequently the safety and performance of medical devices. There will be no changes to the classification in this rule.</p> <p>Rule 5.6 in the Australian MD Regulations for medical devices that are blood bags, is not proposed to be amended.</p>

EU MD Regulation	Australian MD Regulations	Proposed amendments
ANNEX VIII - CLASSIFICATION RULES Chapter III - Classification Rules	Schedule 2 - Classification rules for medical devices other than IVD medical devices Part 2 - Rules for non-invasive medical devices	
4.3 - Rule 3 <i>(first paragraph)</i> <p>All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.</p>	2.3 - Non-invasive medical devices intended to modify the biological or chemical composition of blood, etc. <p>(1) Subject to subclause (2), a non-invasive medical device that is intended by the manufacturer to be used to modify the biological or chemical composition of blood, other body liquids, or other liquids intended to be infused into a patient, is classified as Class IIb.</p> <p>(2) If the treatment for which the device is designed consists of filtration, centrifugation or exchanges of gas or heat, the device is classified as Class IIa.</p>	<p>It is proposed to consider whether some drafting differences should be clarified.</p> <p>As above, this paragraph in the EU MD Regulation clarifies applicability of this rule to non-invasive devices intended for modifying the biological or chemical composition of human tissues and cells.</p> <p>The TGA proposes replicate the effect of the first paragraph of Rule 3 of the EU MD Regulation.</p>
4.3 - Rule 3 <i>(second paragraph)</i> <p>All non-invasive devices consisting of a substance or a mixture of substances intended to be used <i>in vitro</i> in direct contact with human cells, tissues or organs taken from the human body or used <i>in vitro</i> with human embryos before their implantation or administration into the body are classified as class III.</p>	N/A	<p>This classification rule is the subject of this consultation paper and it is proposed to introduce a new classification rule.</p> <p>As discussed in this consultation paper, the TGA proposes to reflect the effect of this rule in the Australian MD Regulations.</p>

Appendix B - Examples

Medical devices covered by the second paragraph of EU MD Regulation Rule 3:

- Assisted reproduction procedure dishes
- *In vitro* fertilization culture medium kit
- *In vitro* fertilization culture medium
- *Ex vivo* cell culture medium
- Tissue storage straw vitrification kit
- Hyaluronan binding sperm selection device
- Organ preservation solution
- Corneal storage medium
- Cultured skin autograft/xenograft
- Blood storage solution, freezing
- Blood donor set, many-pack
- Blood storage solution, nutritional
- Blood storage solution, anticoagulation
- Haemodialysis dialysate solution
- Blood storage solution, freezing
- Bound solute dialysis dialysate
- Blood storage solution, multi-purpose
- Bound solute dialysis system
- Haemodialysis treatment kit

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	March 2019

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Reference/Publication #