Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Proposed changes to the classification of medical devices used in direct contact with the heart, central circulatory or central nervous systems

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 Twenty[1] 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 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 reviews, 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 new classification rules for surgically invasive medical devices intended to be used in direct contact with the heart, central circulatory system or the central nervous system.

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.

[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.

[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

The EU MD Regulation explains that the new requirements increase the robustness of the assessment process, and that the classification rules take into account potential risks associated with 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.

Potential changes: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, consider introducing new classification rules, which are appropriately tailored for the Australian regulatory context, for transient or short-term surgically invasive medical devices used in direct contact with the heart, central circulatory system (CCS) or the central nervous system (CNS).

In the EU MD Regulation these are referred to as: '*surgically invasive devices intended for transient/short-term use … specifically for use in direct contact with the heart or central circulatory system or the central nervous system*'.

Proposals

It is proposed that **new classification rules** be included in Part 3 (Rules for invasive medical devices and implantable medical devices), Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, to align with the **third dot point of Rule 6** and **second dot point of Rule 7** (Annex VIII, Chapter III) of the EU Medical Devices Regulation.

Effect

Classification of **any surgically invasive medical device intended for use in contact with the heart, CCS or the CNS** will be a **Class III (high risk) medical device regardless of the duration of use and/or intended indications**.

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 potential amendments and implementation strategy. Your input will assist us to address any unintended consequences so as to inform the proposal and the regulatory amendment process.

On page 17 is a list of questions to help you address the proposal in your feedback.

Please refer to page 18 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 classification and definitions related to devices used in direct contact with the heart, CCS and CNS?

EU MD Regulation

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

EU Rules 6, 7, and 8 prescribe the classification of particular groups of **surgically invasive devices**. The **first** and **third dot points** of **Rule 6**, the **first** and **second dot points** of **Rule 7**, and the **second** dot point of **Rule 8,**[3] relate to medical devices intended to be used in **direct contact with the heart, CCS** or the **CNS**:

> ***5.2 Rule 6***[4]
>
> *All **surgically invasive devices** intended for **transient use** are classified as class IIa unless they:*
>
> - *are intended specifically to control, diagnose, monitor or correct a defect of the **heart** or of the **central circulatory system** through direct contact with those parts of the body, in which case they are classified as **class III***
>
> *[…]*
>
> - *are intended specifically for use in **direct contact** with the **heart or central circulatory system** or the **central nervous system**, in which case they are classified as **class III***
>
> *[…]*
>
> ***5.3 Rule 7***
>
> *All **surgically invasive devices** intended for **short-term use** are classified as class IIa unless they:*
>
> - *are intended specifically to control, diagnose, monitor or correct a defect of the **heart** or of the **central circulatory system** through direct contact with those parts of the body, in which case they are classified as **class III***
> - *are intended specifically for use in **direct contact** with the **heart** or **central***

[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, 5.2 Rule 6, 5.3 Rule 7, 5.4 Rule 8 (OJ L 117, 5.5.2017, p. 142-143). See also Chapter V, Section 1, Article 51.1 – Classification of Devices, (OJ L 117, 5.5.2017, p. 49).

[4] This rule covers multiple groups of devices, this consultation paper only provides extracts relevant to the subject of this consultation

> ***circulatory system*** *or the* ***central nervous system****, in which case they are classified as* ***class III***
>
> *[…]*
>
> ***5.4 Rule 8***
>
> *All implantable devices and* ***long-term surgically invasive devices*** *are classified as class IIb unless they:*
>
> *[…]*
>
> – *are intended to be used in* ***direct contact*** *with the* ***heart or central circulatory system*** *or the* ***central nervous system****, in which case they are classified as* ***class III***

Article 2 and Annex VIII of the EU MD Regulation provide definitions and other classification rules related to medical devices.

Australia

The classification rules for medical devices are prescribed in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*[5] (the Australian MD Regulations). The rules relevant to surgically invasive medical devices are prescribed in Part 3, Schedule 2 of the Australian MD Regulations.

The relevant classification rules are summarised in 'Current classification of these devices in Australia' (page 13 of this paper).

EU and Australian definitions, classification rules and other provisions

Both the EU MD Regulation and the Australian MD Regulations provide definitions of '*invasive medical device'*, '*surgically invasive medical devices'*, '*central circulatory system*' and '*central nervous system'*.

The TGA is consulting on a proposed alignment between the EU definition '*invasive medical device'* with the provisions in the Australian MD Regulations separately.[6]

For noting

Both the EU MD Regulation and the Australian MD Regulations provide definitions of '*transient*', '*short-term*', and '*long-term*' *use*. The EU MD Regulation also defines the meaning of '*continuous use'*.

For the purposes of calculating the duration, *continuous* means the entire duration of use of the same device without regard to temporary interruption of

[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.

[6] *Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia* https://www.tga.gov.au/consultation/consultation-changes-number-definitions-and-scope-medical-device-regulatory-framework-australia, Appendix A, Table A2, p.15

use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device.[7]

It is proposed to incorporate the definition of '*continuous use*' in the Australian MD Regulations for clarity and consistency purposes.

Transient and short-term surgically invasive medical devices used in direct contact with the heart, CCS or CNS

The EU MD Regulation Rules 6 and 7 provide classification for transient use and short-term use surgically invasive medical devices intended to be used in direct contact with the heart, CCS or CNS.

Classification prior to the amendment

Prior to introducing the EU MD Regulation, transient or short-term surgically invasive medical devices used in direct contact with the heart or the CCS were classified as Class IIa unless the device was intended specifically to control, diagnose, monitor or correct a defect of the heart or the central circulatory system (rules applied under EU Directive 93/42/EEC).[8]

The classification of devices used in direct contact with the heart and CCS in Australia is the same as the rules under the EU Directive 93/42/EEC. However the current classification of transient surgically invasive medical devices used in direct contact with the CNS is different in EU Directive 93/42/EEC and in Australia.

Figures 1 and 2 below provide classification of surgically invasive medical devices used in direct contact with the heart and the central circulatory system, and with central nervous system.

[7] OJ L 117, 5.5.2017, ANNEX VIII, CHAPTER. II, (3.6), p.141.

[8] EU Directive 93/42/EEC, ANNEX IX, III CLASSIFICATION, 2.2 Rule 6, 2.3 Rule 7, 2.4 Rule 8, pp 54-55

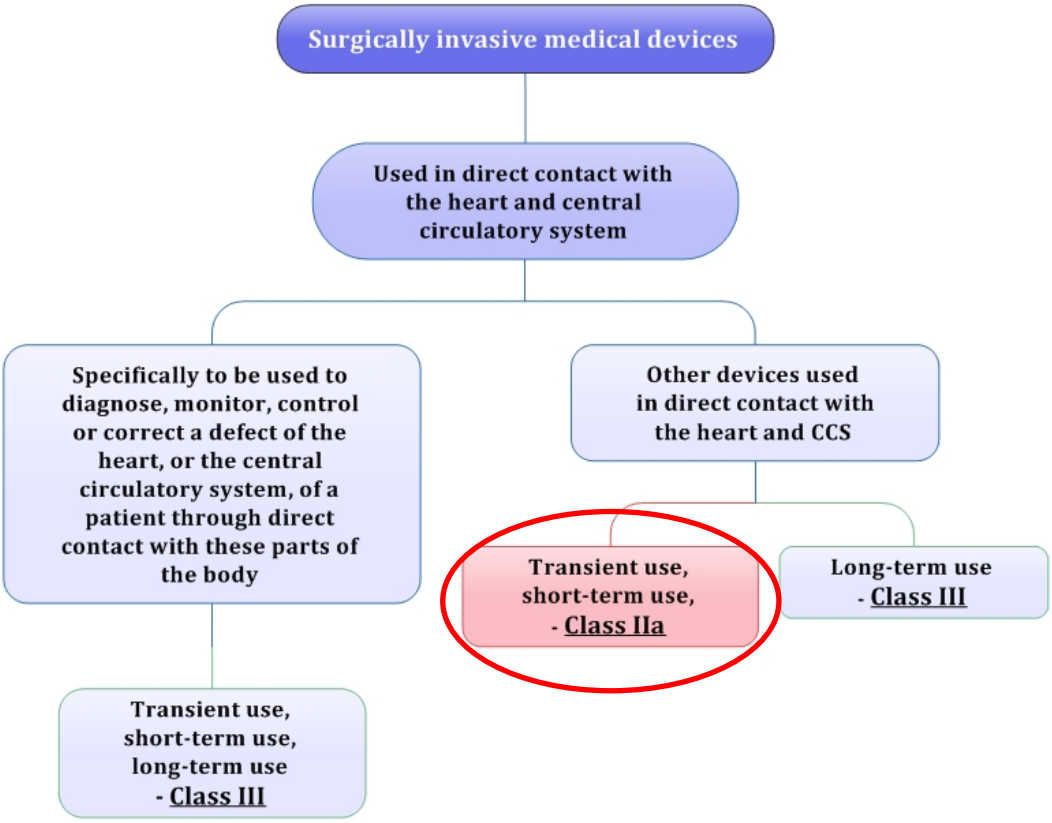

Figure 1: Classification of surgically invasive medical devices used in direct contact with the heart and the central circulatory system

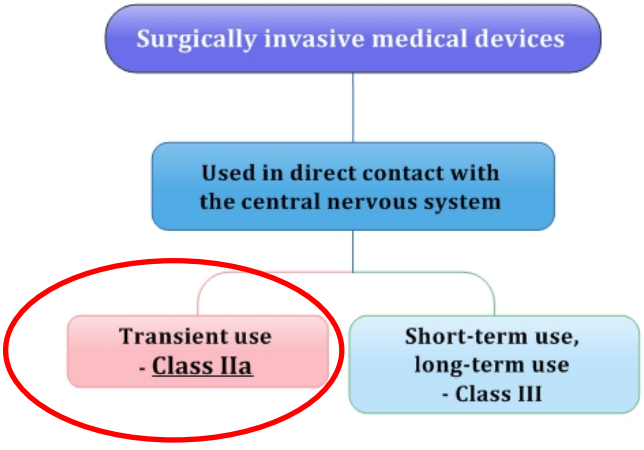

Figure 2: Classification of surgically invasive medical devices used in direct contact with the central nervous system

For noting

This consultation paper is seeking feedback on the **proposed reclassification of transient and short-term surgically invasive medical devices used in**

direct contact with the heart, CCS, or CNS to Class III.

The TGA is not proposing any changes to the devices currently classified as **Class III**.

There is also **no proposal to change the classification of reusable surgical instruments** that are classified as Class I*.

* There will a discussion later in this paper regarding a proposal to change the minimum conformity assessment procedures required for reusable surgical instruments (page 25 of this paper).

Appendix A – Classification rules and definitions (on page 19) has been included as a reference tool. It provides an overview and comparison of the relevant definitions, classification rules, and other provisions applicable to surgically invasive medical devices in the EU and Australian MD Regulations.

Appendix A may help you in providing your feedback.

What are surgically invasive medical devices used in direct contact with the heart, CCS or CNS?

Some examples of transient and short-term surgically invasive medical devices used in direct contact with the heart and/or CCS include: heart valve prosthesis sizer handle, single use; self-expanding valve prosthesis post-dilation balloon catheter; cardiac vent catheter; cardiopulmonary cannulae; etc.

Examples of transient-use surgically invasive medical devices used in direct contact with the CNS include: flexible fibreoptic neuroscope; automatic cranial perforator, single-use; etc.

Further details on these devices are provided in Appendix B – Examples of surgically invasive medical devices used in direct contact with the heart, central circulatory system, or central nervous system (on page 27). Table B also provides clarity on the current classifications of the devices proposed to be reclassified as Class III.

Why reclassify surgically invasive medical devices used in direct contact with the heart, CCS, or CNS?

The location in the body where the devices perform their action is one of the determining factors when deciding on the classification of medical devices.

Definitions of *central circulatory system* and *central nervous system* are provided in Appendix A.

The ***central circulatory system*** consists of the heart and the blood vessels that run throughout the body. The heart pumps blood through the blood vessels of the body via the circulatory system (also called the cardiovascular system) supplying oxygen and nutrients to the tissues and removing carbon dioxide and other metabolic wastes. The central circulatory system is integrated with the heart and enables the blood to reach all parts of the human body to allow the body to survive.

The ***central nervous system*** controls most functions of the body and mind. It consists of the brain and the spinal cord. The brain is responsible for integrating most sensory information and coordinating body function (both consciously and unconsciously); and the spinal cord serves as a conduit for signals between the brain and the rest of the body. If the brain and/or spinal cord

are injured, the exchange of information between the brain and other parts of the body may be disrupted. Damage to the CNS may result in cognitive and physical impairments, difficulties with movement, such as weakness, spasticity, stiffness, and abnormal sensations such as numbness and pain; whilst damage to the optic nerve, which connects the eyes to the brain, may cause blurred vision and loss of colour perception.

Medical devices used in direct contact with the heart, CCS and the CNS can pose significant risks of harm and complications to patients, especially if their designs and/or performance are not fit for purpose.

However, the current classification of some transient and short-term surgically invasive accessories or medical devices intended to be used together with surgically invasive medical devices intended specifically to be used to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, do not reflect this high level of risk, as these devices are not classified as Class III (high-risk).

Accessory to a medical device is a product intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).[9]

Classifying any surgically invasive medical device intended for use in direct contact with the heart, CCS, and CNS as Class III, will ensure the classification appropriately reflects the high-risks associated with the use of these devices, as well as harmonising the Australian MD Regulations with the EU MD Regulation.

Some examples of risks and complications associated with transient and short-term surgically invasive medical devices used in direct contact with the heart, CCS or CNS have been outlined below.

- **Spinal anaesthesia, lumbar puncture – use of spinal needles**

  Spinal needles are used to inject analgesia and/or anaesthetic into the cerebral spinal fluid (CSF) through the membranes surrounding the spinal cord.

  Lumbar puncture is a medical procedure in which a spinal needle is inserted into the spinal canal, most commonly to collect cerebrospinal fluid for diagnostic testing. The main reason for a lumbar puncture is to help diagnose diseases of the central nervous system, including the brain and spine.

  Post lumbar puncture (LP) headache is the most common complication of LP. There are a number of factors that can influence the incidence of post LP headaches, including size of spinal needle, the stylet in the needle used, the type of needle and the orientation of the needle's cutting edge. Other complications of lumber puncture may include failure to obtain a specimen/need to repeat LP/traumatic tap (occurs if the needle inadvertently has entered an epidural vein during insertion); cerebral and spinal herniation, cranial neuropathies, nerve root irritation, low back pain, stylet or needle (for example, fracture of the tip) associated problems, infections, and bleeding complications.

- **Cardiac catheterisation**

  Cardiac catheterisation is a procedure used to diagnose and treat cardiovascular conditions. During cardiac catheterisation, a catheter is inserted into an artery or vein in the groin, neck, or arm, and threaded through the blood vessels to the heart. Other devices can be also

[9] OJ L 117, 5.5.2017, Article 2(2).p. 16

used depending on the procedure (e.g. angioplasty balloon, diathermy electrode, suction tips, etc).

While probability of major complications during cardiac catheterisation procedures can be low, the severity of complications can be very significant. The complication rate depends on multiple factors (including the demographics of the patient, vascular anatomy, co-morbid conditions, clinical presentation, the procedure being performed, and the experience of the operator) with performance of the device being one of the significant impactors. The complications can be minor as discomfort at the site of catheterisation to major ones like death. Local vascular complications can include hematoma/retroperitoneal bleeding, pseudoaneurysm, arteriovenous fistula, dissection and thrombosis/embolism. Other major complications may include myocardial infarction (heart attack), stroke, atheroembolism, allergic reaction, acute renal failure and death.

- **Guidewire-related complications**

  Guidewires are devices designed to navigate vessels to reach a lesion or vessel segment. Once the tip of the device arrives at its destination, it acts as a guide that larger catheters can rapidly follow for easier delivery to the treatment site.

  Guidewire-related complications are rare but potentially serious. The most commonly reported guidewire-related complications include cardiac dysrhythmias, cardiac conduction abnormalities, perforation of vessels or cardiac chambers, kinking, looping, or knotting of the wire, entanglement of previously placed intravascular devices, breakage of the distal tip of the guidewire with subsequent embolization and complete loss of the guidewire within the vascular system. These complications can be a result of kinking or looping of the wire itself, entanglement of a guidewire with an existing intravascular apparatus and inherent design flaws such as tip breakage of a guidewire.

Is amending the classification of any or all of these devices in Australia to Class III appropriate?

Current classification of these devices in Australia

There are currently classification rules related to surgically invasive medical devices intended specifically to be used to diagnose, monitor or correct a defect of the heart or of the CCS through direct contact with these parts of the body; and the rules for the devices that are used in direct contact with the CNS. These classification rules are as follows:

3.2-Surgically invasive medical devices intended for transient use

(1) This clause applies to a surgically invasive medical device that is intended for transient use.

(2) Subject to subclauses (3) to (5), the device is classified as Class IIa.

(3) If the device is intended by the manufacturer specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body, the device is classified as Class III.

(4) If the device is a reusable surgical instrument, the device is classified as Class I.

[…]

3.3-Surgically invasive medical devices intended for short term use

(1) This clause applies to a surgically invasive medical device that is intended for short term use.

(2) Subject to subclauses (3) and (4), the device is classified as Class IIa.

(3) […]

(4) If the device is intended by the manufacturer:

(a) specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body; or

(b) specifically to be used in direct contact with the central nervous system of a patient;

[…] the device is classified as Class III.

[…]

3.4-Surgically invasive medical devices intended for long-term use and implantable medical devices

(1) This clause applies to:

(a) a surgically invasive medical device that is intended for long-term use; and

(b) an implantable medical device.

(2) […][…]If the device is intended by the manufacturer:

(a) to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient;

[…] the device is classified as Class III.

Proposed amendments to the classification rules

If the proposed reclassification takes effect, it will mean that **any surgically invasive medical device intended for use in direct contact with the heart, CCS or the CNS will be classified as Class III.**

There will be no changes to the classification of: transient and short-term surgically invasive medical devices specifically intended to control, diagnose, monitor or correct a defect of the heart or of the CCS through direct contact with those parts of the body; short-term devices used in contact with the CNS and/or long-term surgically invasive medical devices.

There will be no changes to the classification of *reusable surgical instruments*, i.e. classification of these devices will remain as Class I.

Effect of changes for transient and short-term use surgically invasive medical devices

Transient and short-term use surgically invasive medical devices that are not specifically intended by the manufacturer to be used to diagnose, monitor, control or correct a defect of the heart or the CCS, but that are used in direct contact with these parts of the body; and transient use devices that come into contact with the CNS are proposed to be reclassified as Class III high-risk devices.

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[10]. Sponsors will be required to obtain manufacturer's *conformity assessment documents*[11] 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. 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 design and manufacture of better quality, reliable medical devices that are fit for purpose.

Proposed action

It is proposed that **Part 3 (Rules for invasive medical devices and implantable medical devices), Schedule 2** of the *Therapeutic Goods (Medical Devices) Regulations 2002*, be amended, to align with the EU Medical Devices Regulation Rule 6 (1st and 3rd dot points) and Rule 7 (1st and 2nd dot points):

All surgically invasive devices intended for transient use are classified as Class IIa unless:

(a) The device is intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body; or

(b) Any other device intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system;

in which case they are classified as Class III.

All surgically invasive devices intended for short-term use are classified as Class IIa unless:

(a) The device is intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body; or

(b) Any other device intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system;

in which case they are classified as Class III.

[10] *Therapeutic Goods (Medical Devices) Regulations 2002*, r.3.6 and Schedule 3 – Conformity assessment procedures
[11] *Therapeutic Goods Act 1989*, s.3

What will change for sponsors?

If the regulatory changes take effect, sponsors of those surgically invasive devices intended specifically for use in direct contact with the heart or CCS or the CNS that are currently classified at a lower than Class III classification, will be required to apply for inclusion of their medical devices in the ARTG as Class III.

Sponsors who supply, or plan to supply, these devices in Australia will be required to provide manufacturer's *conformity assessment documents* appropriate to medical devices of high-risk classification.[12]

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 Certificate[13] 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 device will be subject to the transitional arrangements** and will have four (4) years to transition (i.e. until August 2024).

Applications

At the date that the proposed amendments take effect:

- All new applications for marketing approval (ARTG inclusion) for any surgically invasive medical device intended specifically for use in direct contact with the heart or CCS, or the CNS submitted to the TGA on or after the date when amended regulations take effect must be for a Class III medical device.
- Sponsors of surgically invasive devices intended specifically for use in direct contact with the heart, CCS or the CNS, already included in the ARTG, that are currently classified at a lower than Class III classification, 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 presently supplied under the existing ARTG entry within six (6) months of

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

[13] 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.

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.

- 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 all surgically invasive medical devices used in direct contact with the heart, CCS or the CNS to Class III are very important to us.

When considering the proposed measures, assume that the EU MD Regulation definitions, terminology, and EU MD Regulation Rules 6 and 7 apply to surgically invasive medical devices 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 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 reclassification of any or all of these devices in Australia to Class III appropriate?
- Do you have any comments/views regarding any definitions or other provisions (refer Appendix A) discussed in this consultation paper?
- Do you have any comments regarding the transitional arrangements proposed in this paper?
- Do you have any other comments regarding these matters?

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 and definitions

Table A below is a comparison of current classification rules, definitions and other provisions by jurisdiction.

EU MD Regulation	Australian MD Regulations	Proposed amendments
ANNEX VIII **CLASSIFICATION RULES**		
CHAPTER I **DEFINITIONS SPECIFIC TO CLASSIFICATION RULES** 1. DURATION OF USE 1.1 'Transient' means normally intended for continuous use for less than 60 minutes. 1.2 'Short term' means normally intended for continuous use for between 60 minutes and 30 days. 1.3 'Long term' means normally intended for continuous use for more than 30 days.	**Schedule 2—Classification rules for medical devices other than IVD medical devices** **Part 1-Interpretation** **1.1 Transient, short-term and long-term use** For this Schedule: (a) a medical device is intended for transient use if the manufacturer intends the device to be used continuously for less than 60 minutes; and (b) a medical device is intended for short-term use if the manufacturer intends the device to be used continuously for at least 60 minutes but not more than 30 days; and (c) a medical device is intended for long-term use if the manufacturer intends the device to be used continuously for more than 30 days.	**For clarity and consistency purposes, we propose to adopt the EU definition of 'transient', 'short-term' and 'long-term' use in the Australian legislation.** In principle, the intent of the definitions in the EU MD Regulation is consistent with our interpretation of the duration of use with respect to 'transient', 'short-term' and 'long-term' use.
CHAPTER II **IMPLEMENTING RULES** 3.6. In calculating the duration referred to in	**Continuous use** is **not defined** in the *Therapeutic Good Act 1989* or *Therapeutic Goods (Medical Devices) Regulations 2002.*	**We propose to adopt the EU MD Regulation definition of 'continuous use' to provide clarity in the**

EU MD Regulation	Australian MD Regulations	Proposed amendments
Section 1, continuous use shall mean: (a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and (b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.		**Australian MD Regulations.**
CHPT. I **2. INVASIVE AND ACTIVE DEVICES** 2.6. '**Central circulatory system**' means the following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens* to the *bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior* and *vena cava inferior*.	**Dictionary** (regulation 1.3) • ***central circulatory system*** means the system in a human being comprising the following vessels: (a) arteriae pulmonales; (b) aorta ascendens; (c) arteriae coronariae; (d) arteria carotis communis; (e) arteria carotis externa; (f) arteria carotis interna;	In Australia, the definition of the central circulatory system extends beyond the EU MD Regulation definition to include the common iliac arteries. It is not proposed to amend the definition in the Australian MD Regulations.

EU MD Regulation	Australian MD Regulations	Proposed amendments
	(g) arteriae cerebrales; (h) trucus brachicephalicus; (i) venae cordis; (j) venae pulmonales; (k) venae cava superior; (l) venae cava inferior; (m) arcus aorta; (n) thoracica aorta; (o) abdominalis aorta; (p) arteriae ilica communis.	
CHPT. I 2.7. '**Central nervous system**' means the brain, meninges and spinal cord.	**Dictionary** (Regulation 1.3) ***central nervous system*** means the system in a human being comprising the brain, meninges and spinal cord.	The EU MD Regulation does not provide 'the system in a human being' in the definition of CNS, however the intent of both provisions is consistent. **No change is proposed.**
CHAPTER III **CLASSIFICATION RULES** **5.2. Rule 6** All **surgically invasive devices intended for transient use** are classified as class IIa unless they: • are intended specifically to control, diagnose,	**Sch. 2, Part 3—Rules for invasive medical devices and implantable medical devices** **3.2—Surgically invasive medical devices intended for transient use** (1) This clause applies to a surgically invasive medical device that is intended for transient use. (2) Subject to subclauses (3) to (5), the device is	**No change is proposed.**

EU MD Regulation	Australian MD Regulations	Proposed amendments
monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; • […]	classified as Class IIa. (3) If the device is intended by the manufacturer specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body, the device is classified as Class III.	
• are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;	N/A	**This classification rule is subject of this consultation paper.**
• are reusable surgical instruments, in which case they are classified as class I;	(4) If the device is a reusable surgical instrument, the device is classified as Class I.	**No change is proposed.**
• are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb; • have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or • are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.	(5) If: (a) the device is intended by the manufacturer to be used to supply energy in the form of ionising radiation; or (b) the device is intended by the manufacturer to have a biological effect; or (c) the device is intended by the manufacturer to be wholly, or mostly, absorbed by the patient's body; or (d) the device is intended by the manufacturer to be used to administer medicine to a patient by means of a	**No change is proposed.**

EU MD Regulation	Australian MD Regulations	Proposed amendments
	delivery system, and the administration is potentially hazardous to the patient having regard to the characteristics of the device; the device is classified as Class IIb.	
CHPT. III **CLASSIFICATION RULES** **<u>5.3. Rule 7</u>** All surgically invasive devices intended for short-term use are classified as class IIa unless they: • are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; • are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;	**Sch. 2, Part 3—Rules for invasive medical devices and implantable medical devices** **3.3—Surgically invasive medical devices intended for short term use** (1) This clause applies to a surgically invasive medical device that is intended for short term use. (2) Subject to subclauses (3) and (4), the device is classified as Class IIa. […] (4) If the device is intended by the manufacturer: (a) specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body; or (b) specifically to be used in direct contact with the central nervous system of a patient; or […] the device is classified as Class III.	**No change is proposed.** **This classification rule is subject of this consultation paper.**

EU MD Regulation	Australian MD Regulations	Proposed amendments
• […]		
5.3. Rule 7 (cont.) All surgically invasive devices intended for short-term use are classified as class IIa unless they: • […] • are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb; • have a biological effect or are wholly or mainly absorbed in which case they are classified as class III; • are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or are intended to administer medicines, in which case they are classified as class IIb.	(3) If: (a) the device is intended by the manufacturer to be used to supply energy in the form of ionising radiation; or (b) the device is intended by the manufacturer to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or (c) the device is intended by the manufacturer to administer medicine; the device is classified as Class IIb. Note for paragraph (b): A device that is intended by the manufacturer to be placed in the teeth, and to undergo a chemical change in the body, is classified as Class IIa—see subclause (2). (4) If the device is intended by the manufacturer: […] (c) to have a biological effect; or (d) to be wholly, or mostly, absorbed by a patient's body;	**No change is proposed.**

EU MD Regulation	Australian MD Regulations	Proposed amendments
	the device is classified as Class III. (5) For this clause, a medical device that is intended by the manufacturer to be placed in the teeth includes a medical device that is intended by the manufacturer to penetrate a tooth, but does not include a medical device that is intended by the manufacturer to penetrate a tooth and enter the gum or bone beyond the tooth.	
CHPT. I 2.3. '**Reusable surgical instrument**' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.	**Dictionary** (regulation 1.3) ***reusable surgical instrument*** means a medical device that is intended by the manufacturer: (a) to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or any other similar procedure; and (b) to be reused after the appropriate procedures specified by the manufacturer in the instructions for use have been carried out.	**It is proposed to consider whether some drafting differences should be clarified.**
Section 2 **Article 52 Conformity assessment procedures** Page 51 (7) Manufacturers of class I devices, other than custom-made or investigational devices, shall	**Regulation 3.9 Class I medical devices (other than medical devices used for a special purpose)** **(1)** Subject to subregulations (2) and (3), the minimum conformity assessment procedures that must be applied to a Class I medical	**It is proposed to amend requirements for the minimum conformity assessment procedures required for reusable surgical instruments consistently with the requirement in the EU MD**

EU MD Regulation	Australian MD Regulations	Proposed amendments
declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or **are reusable surgical instruments**, the Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited: … (c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.	device (other than a medical device used for a special purpose) are the declaration of conformity (not requiring assessment by Secretary) procedures.	**Regulation.**

Appendix B – Examples of surgically invasive medical devices used in direct contact with the heart, CCS, or CNS

Table B – Some examples of devices proposed to be reclassified as Class III

Device	Current Australian MD Regulations classification rule	Proposed classification
B.1 – Surgically invasive medical devices used in direct contact with the heart and central circulatory system		
Heart valve prosthesis sizer handle, single use A hand-held manual surgical instrument intended to be used during cardiac valve repair or replacement as a handle to which an interchangeable valve sizer is attached to allow the surgeon to evaluate the valve opening (patient annulus) into which the appropriate sized annuloplasty ring or replacement valve will be implanted. The device is typically made of metal and/or plastic (e.g. polysulphone) and is straight and/or curved, rigid and/or flexible in design; this handle may also be connected to the valve or ring holder to assist implantation.	3.2(2) and 3.3(2) – Class IIa	Class III
Self-expanding cardiac valve prosthesis post-dilation balloon catheter, single-use device A sterile shaft with an inflatable balloon at its distal end intended to be used during open cardiovascular surgery to dilate the inflow ring of a sutureless cardiac (heart) valve prosthesis, after its implantation and self-expansion, to facilitate valve sealing and anchoring. It typically includes a Luer connector at the proximal end and is available in a variety of sizes to fit with the valve sizes.	3.2(2) - Class IIa	Class III
Cardiac vent catheter, single-use device A thick plastic tube used to decompress a heart chamber during a surgical procedure. It is typically used to decompress the left heart during cardiopulmonary bypass surgery, especially the left ventricle during aortic cross-clamping. It may include a pressure monitoring line to continuously measure the pressure of a chamber.	3.2(2) and 3.3(2) - Class IIa	Class III

Device	Current Australian MD Regulations classification rule	Proposed classification
Central venous catheterization kit, short-term, single-use A collection of sterile devices and materials intended for the short-term (<= 30 days) introduction of a central venous catheter (CVC) for various infusion/aspiration procedures (i.e., non-dedicated). Often referred to as tray, it includes not only a nonimplantable central venous catheter and devices dedicated to catheter introduction/function (e.g., introducer, guidewire), but also includes non-dedicated supportive devices (e.g., drape, dressings, scalpel).	3.3(2) - Class IIa	Class III
B.2 – Surgically invasive medical devices used in direct contact with the central nervous system		
Flexible fibreoptic neuroscope An endoscope that is used for observation, diagnosis and treatment of the central nervous system, and that is inserted through a pre-drilled hole in the cranium. Its insertion portion conforms to body cavities. The image-transmission system is a fibreoptic bundle.	3.2(2) - Class IIa	Class III
Neuroscope, rigid An endoscope that is used for observation, diagnosis and treatment of the central nervous system, and that is inserted through a pre-drilled hole in the cranium. Its insertion portion is rigid. The image-transmission system is relayed lens optics.	3.2(2) - Class IIa	
Automatic cranial perforator, single-use A sterile, drill-like, device designed to cut a circular section, or sections, of the skull vault (calvarium) to provide access to the interior for diagnostic/therapeutic purposes or for the removal of a bone flap for brain surgery. It typically consists of two coaxial drills (one rotating inside the other), a drive shank that enables connection to a powered (either electrical or pneumatic) handpiece, and a built-in clutch mechanism. The inner drill extends slightly beyond the outer cutter in such a way that when the inner drill penetrates the inner table of the skull the clutch mechanism disengages. It is typically made of high-grade stainless steel. This is a single-use device.	3.2(2) - Class IIa	

Device	Current Australian MD Regulations classification rule	Proposed classification
Spinal needle A sharp, bevel-edged device used to administer anaesthetic or analgesic agents intrathecally. It is typically sterile, disposable, fenestrated, and spring-tipped. Device can be used during Lumbar Puncture	3.2(2) – Class IIa 3.2(4) – Class IIb (used to administer medicine)	Class III

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 #