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MTAA Submission to TGA consultation:

Proposed changes to the classification of active implantable medical devices and their accessories

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1. Executive Summary

On 6th March 2019, the TGA opened the consultation: *Proposed changes to the classification of active implantable medical devices and their accessories*. This consultation paper considers the implications of aligning the Australian risk classification rules for accessories of active implantable medical devices (AIMD) with the corresponding risk classification rules in the new EU Regulation on medical devices 2017/745.

The EU classification rules applicable to active implantable devices and their accessories are reproduced below:

> ***ANNEX VIII***
>
> ***Chapter II Implementing Rules***
>
> *3.3 Software, which drives a device or influences the use of a device, shall fall within the same class as the device.*
>
> ***Chapter III Classification Rules***
>
> ***Rule 8***
>
> *'All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:*
>
> *[…] (6th dot point)*
>
> - *are active implantable devices or their accessories, in which cases they are classified as class III'*
>
> ***Rule 9***
>
> *[…] (4th paragraph)*
>
> *'All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.'*

The implication for Australian sponsors is that non-implantable accessories to active implantable medical devices currently classified below class III or AIMD would be up-classified to class III, including low risk non-implantable accessories that are not essential for the ability of the AIMD to be used in accordance with its intended purpose.

The up-classification of these low risk, non-essential accessories to class III and separate inclusion of each individual model in the ARTG would impose unreasonable burden on manufacturers and sponsors, disproportionate with their intrinsic risk.

It is our understanding that the EU Medical Device Coordination Group (MDCG) will soon commence work on MDR classification guidance and that Rule 8 is a top priority for manufacturers. MedTech Europe confirmed to us that they added Rule 8 to their list of classification priorities recently submitted to the Commission.

We expect that the MDCG will rule in favor of classifying low risk, non-implantable accessories to AIMDs, that enable the AIMDs to be used in accordance with their intended purpose but that are not essential for the AIMDs function, in their own right.

MTAA submits that the TGA risk classification of low risk, non-implantable and non-essential accessories should remain aligned with the EU MDR classification guidance (once published). Until then we recommend that these accessories to AIMDs be specifically excluded from up-classification to class III. A detailed discussion including examples is provided in the next sections.

2. Definitions and implementing rules

The definitions and implementing rules from the EU MDD, EU AIMDD, EU MDR, Australian TG Act and regulations that are applicable to accessories of medical devices, including active implantables, are reproduced, with added emphases, in Table 1 for easy reference.

Table 1: Definitions and implementation rules from European and Australian regulations

Regulations	Definitions and implementing rules
EU AIMD Directive 90/385/EEC[1]	**Article 1(2) (a)**: 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any **accessories or software** for its proper functioning, intended by the manufacturer to be used for human beings [...] Accessories are, by definition, medical devices and are classified as AIMDs.
EU MD Directive 93/42/EEC[2]	**Article 1(2) (b)**: **'accessory'** means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device; Accessories are treated as medical devices and are classified in their own right.
EU MDR 2017/745[3]	**Article 2(2)**: **'accessory for a medical device'** means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or

[1] Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31990L0385

[2] Council Directive 93/42/EEC of 14 June 1993 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042

[3] Regulation (EU) 2017/745 on medical devices, 5 April 2017: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

Regulations	Definitions and implementing rules
	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);" **Rule 8**: All implantable devices and long-term surgically invasive devices are classified as class IIb unless they are active implantable devices or their **accessories**, in which case they are classified as class III. **Rule 9**: All **active devices** that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III. **Implementation rule 3.2**: If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. **Accessories** for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used. **Implementation rule 3.3**: **Software**, which drives a device or influences the use of a device, shall fall within the same class as the device.
AU TG Act 1989[4]	**Chapter 1 – Preliminary, 3 Interpretation**: (1) **accessory**, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab), means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended.
AU TG (Medical Devices) Regulations 2002[5]	**Part 3 – Conformity assessment procedures, Division 3.1 – Medical device classifications, 3.3 Principles for applying the classification rules**: (4) An **accessory** to a medical device is classified separately from the medical device. **Schedule 2 – Classification rules for medical devices other than IVD medical devices, Part 5 -Special rules for particular kinds of medical devices, 5.7 Active implantable medical devices**: (2) An **implantable accessory** to an active implantable medical device is classified as Class III. (3) An **active medical device** that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.

[4] Therapeutic Goods Act 1989, Compilation No. 72 of 1 January 2019: https://www.legislation.gov.au/Details/C2019C00066

[5] Therapeutic Goods (Medical Device) Regulations 2002, Compilation No. 39 of 1 December 2018: https://www.legislation.gov.au/Details/F2018C00899

Class AIMD and class III are equivalent in terms of regulatory oversight, therefore it *appears* that there is no change in the way accessories of active implantable medical devices, including software, are regulated in the new EU MDR compared with the old EU AIMD Directive.

The EU MDR clarifies that active devices that are intended for controlling, monitoring or directly influencing the performance of AIMDs are classified as class III, and software which drives a device or influences the use of a device is classified in the same class as the device.

Accessories to medical devices other than active implantable continue to be classified in their own right in the EU MDR, hence there is no change from the old EU MDD.

The Australian regulations state currently that implantable accessories and active devices (this includes software) that are accessories to AIMDs are classified as class III, and all other accessories are classified in their own right.

A strictly literal interpretation of the text in the Rule 8 of the EU MDR would mean that, to fully align with the EU MDR risk classification, non-implantable accessories other than software would need to be up-classified to class III. However, Rule 8 does not distinguish between non-implantable accessories that are essential and those that are not essential for the AIMD function.

We are confident that the EU MDCG will clarify this in a satisfactory manner and rule that low risk non-implantable accessories which are not essential for the function of AIMDs should be classified in their own right, in the same way that other accessories to medical devices are classified.

3. Essential vs non-essential accessories

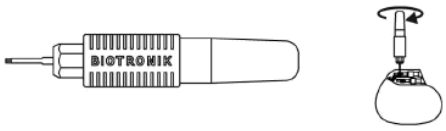
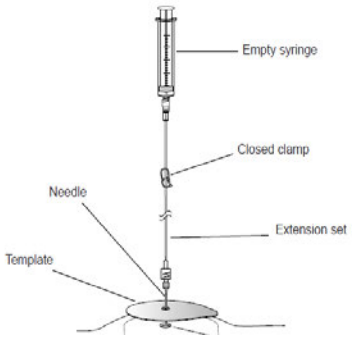
An 'accessory' is defined by the EU MDR as "an article, which whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to **specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s)** or to **specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)**" (emphasis added).

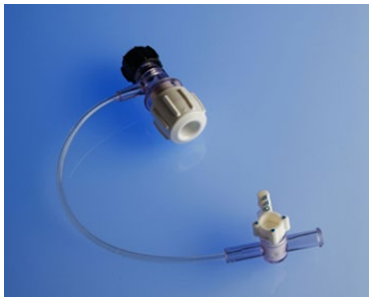
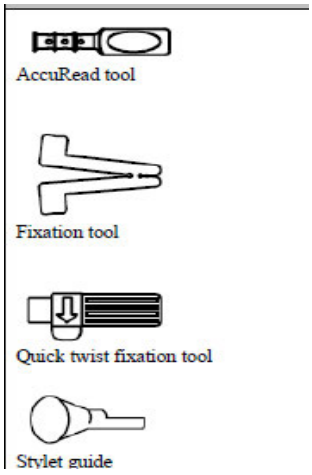
Non-implantable accessories provided merely to improve device ergonomics, to enhance cosmetic appearance, or to enhance patient comfort and lifestyle are low risk and obviously not essential for the ability of the medical device to be used in accordance with its intended purpose, neither do they specifically assist the medical device functionality.

Such non-implantable low risk accessories can be provided together with or separately for active implantable medical devices, and EU notified bodies have accepted in the past to classify them below class III or AIMD. Table 2 shows a few examples provided by MTAA members.

Table 2: Examples of non-implantable low risk, non-accessories provided by MTAA members

	MED-EL detachable covers in various designs for audio processor coils
 	MED-EL audio processor waterproof covers for dust and water protection (not considered a medical device in the EU)
 	MED-EL ear hook made of soft plastic for wearing behind the ear to better hold the audio processor in place; the ear hook is secured to the audio processor with a pin which can be removed with a dedicated pin removal tool
	MED-EL audio processor remote control used as a user-friendly option for optimizing audio processor use in changing daily listening situations

TW 	Biotronik screwdriver with torque control used to connect Biotronik leads or accessories to the IS-1, DF-1 IS4 or DF4 connectors compatible with the corresponding lead connector for a Biotronik pacemaker or ICD.
	Medtronic external patient programmer antenna used as signal booster for patient programmer
	Medtronic pump refill kits (implant tool kit) intended for use in accessing the catheter access port and/or refilling implantable infusion pumps used in pain management for delivery of drugs
	Medtronic single-use tunneling tool intended for subcutaneous insertion to create a route that facilitates the implant of a lead, used in conjunction with an introducer sheath
	Medtronic pacemaker system analyzer – magnet placed over the pacemaker/ defibrillator to switch it to a non-sensing or non-detection mode in situations such as surgery, where an external power source, e.g. diathermy, may interfere with the function of the pacemaker/ defibrillator

	Medtronic adjustable haemostasis valve, intended for use with the Medtronic Attain Lead delivery system to reduce blood loss during the lead implant procedure
	Medtronic insertion tool (part of a tool kit), used to insert an insertable cardiac monitor (ICM)
	Medtronic single-use lead accessory kit, used in implant procedures for Medtronic leads with four pole inline connectors
Medtronic Sterile RF head cover (no image available)	Medtronic sleeve providing sterile protection of a non-sterile programming head of an AIMD programmer, used in a situation where the sterile field must be maintained to protect the patient from infection or contamination.
Medtronic Implant tool kits	Medtronic surgical instruments and materials used to perform a neurosurgical procedure

Accessories to active implantable medical devices are typically designed to match only the manufacturer's own active implantable medical devices, i.e., they are not compatible/ interchangeable with accessories of similar active implantable medical devices. Such customization helps contain any real or perceived risks in relation to non-implantable low risk accessories being used with active implantable devices.

In Europe, accessories can be listed on the EC Design Examination Certificate issued for the active implantable medical device, hence the need to be able to uniquely identify them by model designation or catalog number can be achieved at a relatively low additional cost. Individual unique identification for accessories is needed when the manufacturer wants to have the option to supply them separately and needs direct traceability to a marketing approval.

By contrast, Australian regulations require that class III/AIMD devices are individually entered in the ARTG so that they can be traced by individual model designation or catalog number. Should non-implantable low risk accessories be up-classified to class III, the costs of including them in the ARTG and the cost of maintaining the ARTG entries would increase by an order of magnitude which doesn't justify the actual level of risk.

Accessories to active implantable medical devices are usually tested and validated as part of a system, and they rarely if ever have separate technical documentation files. The effort to 'unpick' technical documentation from the system to create separate files would be significant but for very little gain in real terms and no added value for patient safety.

A future Unique Device Identification (UDI) would address medical device traceability at all risk levels, not just for high risk devices. However, until an UDI system is implemented in Australia, there are interim solutions that can be implemented to increase transparency for accessories of active implantable medical devices.

4. Spare parts

The EU MEDDEV 2.1/1 guidance[6] states:

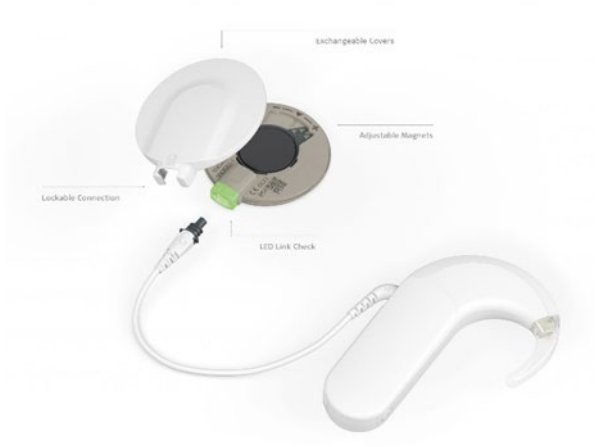
> "*Spare parts supplied for replacement of existing components of a device, the conformity of which has already been established, are not medical devices. If spare parts, however, change significantly the characteristics or performances of a device with regard to its already established conformity, such spare parts are to be considered as devices in their own right.*"

Spare parts supplied separately to replace parts of non-implantable accessories or parts of a system classified as active implantable medical device should not be considered medical devices or accessories requiring up-classification to as class III.

A possible way to manage spare parts would be to label them as "spare part for [device designation/ catalog number], ARTG [ARTG number]". Table 3 shows a few examples provided by MTAA members.

[6] European Commission Guidance documents -0 Definitions of "medical devices", "accessory" and "manufacturer" – MEDDEV 2.1/1, April 1994: https://ec.europa.eu/docsroom/documents/10278/attachments/1/translations

Table 3: Examples of spare parts/ components of non-implantable accessories to AIMDs provided by MTAA members

	MED-EL components of the external audio processor that can be provided separately: detachable coil cable available in various lengths, coil cover, coil magnet
(no images provided)	Any components and spare parts provided separately to service and repair external parts of an AIMD

In conclusion, MTAA submits that once the EU MDCG risk classification guidance for EU MDR Rule 8 is published, the TGA risk classification of low risk, non-implantable and non-essential accessories should remain aligned with the EU risk classification guidance. Until then we recommend that these accessories to AIMDs be specifically excluded from up-classification to class III.