



## **Therapeutic Goods (Medical Devices— Application Form for Inclusion) Approval (No. 2) 2021**

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I, Meryl Clarke, as delegate of the Secretary of the Department of Health, make the following approval.

Dated 30 September 2021

Meryl Clarke  
Assistant Secretary  
Medical Devices Authorisation Branch  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Application Form for Inclusion) Approval (No. 2) 2021*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information        |                |                |
|---------------------------------|----------------|----------------|
| Column 1                        | Column 2       | Column 3       |
| Provisions                      | Commencement   | Date/Details   |
| 1. The whole of this instrument | 1 October 2021 | 1 October 2021 |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 41FDB(2) of the Act.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) kind, in relation to a medical device;
- (b) included in the Register;
- (c) medical device.

In this instrument:

*Act* means the *Therapeutic Goods Act 1989*.

**active implantable medical device** or **AIMD** has the same meaning as in the Regulations.

**application** means an application to the Secretary for a kind of medical device to be included in the Register under section 41FC of the Act.

**Class 1 IVD medical device** means an IVD medical device that is classified under the Regulations as a Class 1 IVD medical device.

**Class 2 IVD medical device** means a medical device that is classified under the Regulations as a Class 2 IVD medical device.

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***Class 3 IVD medical device*** means a medical device that is classified under the Regulations as a Class 3 IVD medical device.

***Class 4 IVD medical device*** means a medical device that is classified under the Regulations as a Class 4 IVD medical device.

***Class 4 in-house IVD medical device*** means a medical device that is classified under the Regulations as a Class 4 in-house IVD medical device.

***Class I medical device*** means a medical device that is classified under the Regulations as a Class I medical device.

***Class IIa medical device*** means a medical device that is classified under the Regulations as a Class IIa medical device.

***Class IIb medical device*** means a medical device that is classified under the Regulations as a Class IIb medical device.

***Class III medical device*** means a medical device that is classified under the Regulations as a Class III medical device.

***Class AIMD medical device*** means a medical device that is classified under the Regulations as a Class AIMD medical device.

***IVD medical device***, or in vitro diagnostic medical device, has the same meaning as in the Regulations.

***measuring function*** has the same meaning as in the Regulations.

***Regulations*** means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

***TGA Business Services*** means TGA Business Services on the Therapeutic Goods Administration website which may be accessed on the internet at <https://business.tga.gov.au>.

***Therapeutic Goods Administration*** means that part of the Department known as the Therapeutic Goods Administration.

## **5 Approved forms—medical devices other than IVD medical devices**

### ***Class I medical devices***

- (1) The approved form for an application relating to a Class I medical device that:
  - (a) does not have a measuring function; and
  - (b) is intended by the manufacturer to be supplied in a non-sterile state; and
  - (c) is not intended by the manufacturer to be for export only;is the online application form for the class identified as *Class I* accessed via the *Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

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- (2) The approved form for an application relating to a Class I medical device that:
- (a) has a measuring function; and
  - (b) is intended by the manufacturer to be supplied in a non-sterile state; and
  - (c) is not intended by the manufacturer to be for export only;
- is the online application form for the class identified as *Class I Measurement* accessed via the *Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.
- (3) The approved form for an application relating to a Class I medical device that:
- (a) is intended by the manufacturer to be supplied in a sterile state; and
  - (b) is not intended by the manufacturer to be for export only;
- is the online application form for the class identified as *Class I Sterile* accessed via the *Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.
- (4) The approved form for an application relating to a Class I medical device that is intended by the manufacturer to be for export only is the online application form for the class identified as *Class I* accessed via the *Medical Device – Included (Export Only)* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

*Class IIa medical device*

- (5) The approved form for an application relating to a Class IIa medical device is the online application form for the class identified as *Class IIa* accessed via the *Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

*Class IIb medical device*

- (6) The approved form for an application relating to a Class IIb medical device is the online application form for the class identified as *Class IIb* accessed via the *Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

*Class III medical device*

- (7) The approved form for an application relating to a Class III medical device is the online application form for the class identified as *Class III* accessed via the *Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

*Class AIMD medical device*

- (8) The approved form for an application relating to a Class AIMD medical device is the online application form for the class identified as *AIMD* accessed via the

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*Medical Device – Included* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

Note: For TGA Business Services, see section 4.

## **6 Approved forms—IVD medical devices**

### *Class 1 IVD medical device*

- (1) The approved form for an application relating to a Class 1 IVD medical device that is not intended by the manufacturer to be for export only is the online application form for the class identified as *Class 1* accessed via the *Medical Device – IVD* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.
- (2) The approved form for an application relating to a Class 1 IVD medical device that is intended by the manufacturer to be for export only is the online application form for the class identified as *Class 1* accessed via the *Medical Device – IVD (Export Only)* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

### *Class 2 IVD medical device*

- (3) The approved form for an application relating to a Class 2 IVD medical device is the online application form for the class identified as *Class 2* accessed via the *Medical Device – IVD* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

### *Class 3 IVD medical device*

- (4) The approved form for an application relating to a Class 3 IVD medical device is the online application form for the class identified as *Class 3* accessed via the *Medical Device – IVD* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

### *Class 4 IVD medical device*

- (5) The approved form for an application relating to a Class 4 IVD medical device is the online application form for the class identified as *Class 4* accessed via the *Medical Device – IVD* item within the *Device/OTG Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

### *Class 4 in-house IVD medical device*

- (6) The approved form for an application relating to a Class 4 in-house IVD medical device is the online application form for the class identified as *Class 4* accessed via the *Medical Device – IVD Class 4 In-House* item within the *Device/OTG*

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*Application* link in TGA Business Services, as in force or existing at the commencement of this instrument.

Note: For TGA Business Services, see section 4.

## **7 Repeals**

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

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## **Schedule 1—Repeals**

### ***Therapeutic Goods (Medical Devices—Application Form for Inclusion) Approval 2021***

#### **1 The whole of the instrument**

Repeal the instrument.