



Therapeutic Goods (Medical Devices— Application Form for Priority Applicant Determinations) Approval 2020

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

Dated 9 December 2020

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 Priority Applicant Determinations) Approval 2020*.

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	The day after this instrument is made.	10 December 2020

Note: This table relates only to the provisions of this instrument as originally made.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 subregulations 4.3B(2) and 5.4A(2) of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Definitions

Note 1: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) medical device.

Note 2: A number of expressions used in this instrument are defined in the Dictionary at the end of the Regulations, including the following:

- (a) conformity assessment (priority applicant) determination; and
(b) medical devices (priority applicant) determination.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

5 Approved form

- (1) The approved form for an application under subregulation 4.3B(1) of the Regulations for a conformity assessment (priority applicant) determination in relation to a medical device is the form titled *Application for priority applicant*

determination - medical devices published on the Therapeutic Goods Administration's website.

- (2) The approved form for an application under subregulation 5.4A(1) of the Regulations for a medical devices (priority applicant) determination in relation to a medical device is the form titled *Application for priority applicant determination - medical devices* published on the Therapeutic Goods Administration's website.

Note: The Therapeutic Goods Administration's website can be accessed at <https://www.tga.gov.au>.