



Therapeutic Goods (Application Form for Conformity Assessment Body Determination) Approval 2021

I, Tracey Duffy, as delegate of the Secretary of the Department of Health, make the following approval.

Dated 1 July 2021

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Application Form for Conformity Assessment Body Determination) Approval 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	The day this instrument is made.	1 July 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Note: This table relates only to the provisions of this instrument as originally made.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 subregulation 4A.2(4) of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Definitions

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

- (a) conformity assessment body determination;
- (b) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

Therapeutic Goods Administration has the same meaning as in the *Therapeutic Goods Regulations 1990*.

5 Approved forms

For the purposes of subparagraphs 4A.2(2)(a)(ii) and (iii) of the MD Regulations, the approved form for making an application to the Secretary for a conformity assessment body determination is the online application form accessed via the *Application for Determination of Australian Conformity Assessment Bodies* link on the *Australian Conformity Assessment Bodies* page under the *Medical Devices & IVDs* heading in the *Industry* tab on the Therapeutic Goods Administration website.

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