



Therapeutic Goods (Custom-Made Medical Devices—Annual Reporting Form) Approval 2021

I, Kate McCauley, as delegate of the Secretary of the Department of Health, make the following approval.

Dated 30 June 2021

Kate McCauley
Assistant Secretary
Medical Devices Surveillance Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Custom-Made Medical Devices—Annual Reporting Form) 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	1 July 2021.	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Note: This table relates only to the provisions of this instrument as originally made.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 regulation 10.3A of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Definitions

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

- (a) Secretary.

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) custom-made medical device.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

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

5 Approved form

The approved form for providing a report under regulation 10.3A of the Regulations to the Secretary, is the online form accessed via the *Annual Reporting Form – Custom-made medical devices* link on the *Custom-made medical devices* page on the Therapeutic Goods Administration website.

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