



Therapeutic Goods (Medical Devices— Arrangement for Computer Programs) Instrument 2020

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

Dated 25 September 2020

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

Contents

1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Definitions	1
5 Arrangement for computer programs.....	2
6 Repeals.....	2
Schedule 1—Arrangement for computer programs	3
Schedule 2—Repeals	4

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Arrangement for Computer Programs) Instrument 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	1 October 2020.	1 October 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 7C(1) of the *Therapeutic Goods Act 1989*.

4 Definitions

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

- (a) kind;
- (b) medical device;
- (c) Register.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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 Arrangement for computer programs

For subsection 7C(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the use of the computer program mentioned in column 2, is arranged for the purposes mentioned in column 3.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed.

Schedule 1—Arrangement for computer programs

Note: See section 5.

Arrangement for use of computer programs to make decisions		
Column 1	Column 2	Column 3
Item	Computer program	Purposes
1	TGA Business Services	any purpose in relation to the making of the following decisions under section 41FDB of the Act: <ul style="list-style-type: none">(a) carrying out an assessment under subsection 41FDB(1) of the Act as to whether the requirements set out in subsection 41FDB(2) of the Act have been met;(b) deciding that an application passes preliminary assessment under subsection 41FDB(3) of the Act;(c) refusing an application that has not passed preliminary assessment under subsection 41FDB(4) of the Act
2	TGA Business Services	any purpose in relation to the making of the following decisions under section 41FF of the Act: <ul style="list-style-type: none">(a) including a kind of medical device in the Register in accordance with subsection 41FF(1) of the Act;(b) making available a certificate of the inclusion of a kind of medical device in the Register in accordance with subsection 41FF(2) of the Act
3	TGA Business Services	any purpose in relation to the making of the following decisions under section 41FH of the Act: <ul style="list-style-type: none">(a) selecting for auditing an application for a kind of medical device to be included in the Register in accordance with subsection 41FH(1) of the Act;(b) giving a selection notice in accordance with subsection 41FH(2) of the Act

Schedule 2—Repeals

Note: See section 6.

Repeal of instruments			
Column 1	Column 2	Column 3	Column 4
Item	Name of instrument	Delegate	Date of making
1	Arrangement made under subsection 7C(1) of the Act in relation to decisions under subsection 41FF(1) of the Act	Judy Develin	24 February 2011
2	<i>Therapeutic Goods (Use of a computer program for export only medical devices) Arrangement 2018</i>	Hongxia Jin	18 October 2018
