Therapeutic Goods (Australian Breast Device Registry) Specification 2019

I, Ben Noyen, as delegate of the Minister for Health, make the following specification.

Dated 26 July 2019

Ben Noyen
Acting First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Australian Breast Device Registry) Specification 2019*.

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 registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 61(5AB) 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) device number;
(b) manufacturer;
(c) Register;
(d) Secretary; and
(e) therapeutic goods.

In this instrument:

ABDR means the Australian Breast Device Registry administered by Monash University (ABN 12 377 614 012).

Act means the *Therapeutic Goods Act 1989*.

breast device means one of the following medical devices, or kinds of medical device:

(a) breast implant;
(b) acellular dermal matrix;

(c) tissue expander.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

5 Release of therapeutic goods information

For subsection 61(5AA) of the Act, in relation to each item, the kinds of therapeutic goods information specified in column 2 of the table in Schedule 1 to this instrument, may be released to the body specified in column 3, for the purposes specified in column 4 of that table.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a body that is specified under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

Schedule 1—Therapeutic goods information

Note: See section 5.

Therapeutic goods information that may be released			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Information**	**Body**	**Purposes**
1	in relation to a breast device, the following information on an annual basis: (a) the name of the breast device; (b) the classification of the breast device; (c) the model number of the breast device; (d) the device number (commonly known as the ARTG number) of the breast device; (e) the manufacturer of the breast device; (f) the raw sales data relating to the breast device	ABDR	both of the following: (a) determining the number of devices registered with the ABDR as a proportion of those supplied in the Australian market (the ***capture rate***); and (b) publishing the aggregate capture rate in the annual report of the ABDR