

**Therapeutic Goods (Breast Implants Information) Specification 2019**

I, John Skerritt, as delegate of the Minister for Health, make the following specification.

Dated 9 July 2019

Adjunct Professor John Skerritt

Deputy Secretary

Health Products Regulation Group

Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Breast Implants Information) 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Note: This table relates only to the provisions of this instrument as originally made.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(5D) 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:

1. device number;
2. manufacturer, of a medical device;
3. medical device;
4. Register;

(e) sponsor; and

(f) therapeutic goods.

In this instrument:

***Act*** means *Therapeutic Goods Act 1989*.

***breast implant device*** means a medical device which is intended for the purpose of implantation as a breast implant, mammary implant or tissue expander (however described).

***relevant regulatory action*** means one or more of the following actions by a delegate of the Secretary:

(a) giving notice of a proposal to suspend a kind of medical device from the Register under Part 4-6 of the Act;

(b) giving notice of a proposal to cancel the entry of a kind of medical device from the Register under Part 4-6 of the Act;

(c) the imposition of new conditions on including a kind of device in the Register under section 41FP of the Act.

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

5 Therapeutic goods information

The kinds of therapeutic goods information set out in column 2 of the table in Schedule 1 to this instrument, as described in column 3 of the corresponding item, are specified for the purpose of subsection 61(5C) of the Act.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C).

Schedule 1—Specified kinds of therapeutic goods information

Note: See section 5.

| Kinds of therapeutic goods information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Item | Information | Description |
| 1 | therapeutic goods | the name (including the brand name), and device number (commonly known as the ARTG number), of the breast implant device that is the subject of relevant regulatory action (the ***relevant goods***), and any other information necessary to identify the relevant goods |
| 2 | sponsor | the name of the sponsor of the relevant goods |
| 3 | manufacturer | the name of the manufacturer of the relevant goods |
| 4 | relevant regulatory action | details of the relevant regulatory action in relation to the relevant goods, including the date that the decision in relation to the relevant regulatory action was made |