Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Information (Medical Devices) Specification 2017

Therapeutic Goods Act 1989

I, JOHN SKERRITT a delegate of the Minister for Health, make this Specification, under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

Dated 29 August 2017

(signed by)

JOHN SKERRITT
Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information* (*Medical Devices) Specification 2017.*

2 Commencement

This Specification commences on the day after it is registered.

3 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

Specified medical device means an implantable medical device or an active implantable medical device

Note: 'active implantable medical device' has the same meaning as in the Dictionary to the Therapeutic Goods (Medical Devices) Regulations 2002;

'implantable medical device' has the same meaning as in the Dictionary to the Therapeutic Goods (Medical Devices) Regulations 2002;

'medical device' has the same meaning as in s 41BD of the Act; and

'therapeutic goods information' has the same meaning as in s 61 of the Act. This information is expressly limited to information held by the Department; it does not include information that the Department does not hold, for example, information held only by a manufacturer.

4 Specification

For subsection 61(5AA) of the Act, Schedule 1 specifies the kinds of persons in column 1 to whom the kinds of therapeutic goods information specified in column 2 can be released for the purposes specified in column 3.

Note: The therapeutic goods information specified in Schedule 1 can be released by the Secretary to a person specified in Schedule 1 under subsection 61(5AA) of the Act.

Schedule 1 Specification

(section 4)

	Column 1 (Kinds of person)	Column 2 (Kinds of therapeutic goods information)	Column 3 (Purposes)
1	Any person who has been or may have been implanted with a specified medical device.	Information regarding the materials, including their chemical and physical properties, used in the production of the specified medical device (or generally used in the type of specified medical device), including possible residues of the materials.	For the purpose of informing a person about a specified medical device that has been or may have been implanted in that person.
2	Any medical practitioner who has treated or is treating any person who has been or may have been implanted with a specified medical device.	Information regarding the materials, including their chemical and physical properties, used in the production of the specified medical device (or generally used in the type of specified medical device), including possible residues of the materials.	For the purpose of informing (a) that medical practitioner about a specified medical device that has been or may have been implanted in a patient of the medical practitioner, or (b) that patient.