



# **Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018**

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I, Hongxia Jin, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 19 December 2018

Hongxia Jin  
Acting Assistant Secretary  
Medical Devices Branch  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*.

## 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.

<b>Commencement information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
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Note: This table relates only to the provisions of this instrument as originally made.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 41FDB(7) of the Act.

## 4 Amendments

Each instrument that is specified in a Schedule to this instrument is amended as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## Schedule 1—Amendments

### *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

#### 1 Section 4

Insert:

*ISO 13485* means International Standard ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*, issued by the International Organization for Standardization in March 2016, as in force or existing immediately before the commencement of this instrument.

Note: ISO 13485 is published at: <https://www.iso.org>.

#### 2 Part 1 of Schedule 2 (table item 2)

Repeal the item, substitute:

- |   |  |  |
|---|--|--|
| 2 | a notified body within the meaning of Directive 98/79/EC | one of the following:<br>(a) a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC;<br>(b) a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC; or<br>(c) a document certifying compliance with ISO 13485 |
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#### 3 Part 2 of Schedule 2 (table item 3)

Repeal the item, substitute:

- |   |  |   |
|---|--|---|
| 3 | a notified body within the meaning of Directive 98/79/EC | either of the following:<br>(a) a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC; or<br>(b) a document certifying compliance with ISO 13485 |
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