Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019

I, Miranda Lauman, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 8 April 2019

Miranda Lauman
Assistant Secretary
Medical Devices Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 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Note: This table relates only to the provisions of this instrument as originally made.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 41FDB(7) of the *Therapeutic Goods Act 1989*.

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.

Schedule 1—Amendments

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

1 Section 3

Omit "Act", substitute "*Therapeutic Goods Act 1989*".

2 Section 4

Insert:

IAF accredited conformity assessment body means a body that is accredited to undertake certification for compliance with ISO 13485 by an accreditation body member that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum, Inc., otherwise known as the IAF MLA.

3 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: (a) a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC; (b) a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC; or (c) for an application submitted before 26 May 2022—a document certifying compliance with ISO 13485

4 Part 1 of Schedule 2 (table item 4)

Repeal the item, substitute:

4	Health Canada	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Canadian medical devices regulations

5 Part 1 of Schedule 2 (table item 6)

Repeal the item, substitute:

6	recognised auditing organisation	a MDSAP certificate

6 Part 1 of Schedule 2 (at the end of the table)

Add:

7	an IAF accredited conformity assessment body	for an application submitted before 26 May 2022—a document certifying compliance with ISO 13485

7 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: (a) a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC; or (b) for an application submitted before 26 May 2022—a document certifying compliance with ISO 13485

8 Part 2 of Schedule 2 (table item 7)

Repeal the item, substitute:

7	Health Canada	either of the following: (a) a MDSAP certificate; or (b) a quality management system certificate for the purposes of the Canadian medical devices regulations

9 Part 2 of Schedule 2 (at the end of the table)

Add:

11	an IAF accredited conformity assessment body	for an application submitted before 26 May 2022—a document certifying compliance with ISO 13485