Therapeutic Goods Amendment (Overseas Regulators) 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 (Overseas Regulators) 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Note: This table relates only to the provisions of this instrument as originally made.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 41BIB(2) 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 (Overseas Regulators) 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.

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.

3 Section 5

Insert:

(aa) an IAF accredited conformity assessment body;

4 Paragraph 5(e)

Omit "and".