



Therapeutic Goods (Overseas Regulators) Determination 2018

I, Hongxia Jin, Acting Assistant Secretary, Medical Devices Branch, a delegate of the Secretary of the Department of Health, make the following determination.

Dated 10 September 2018

(Signed by)

HONGXIA JIN

Delegate of the Secretary of the Department of Health

1 Name

This instrument is the *Therapeutic Goods (Overseas Regulators) 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.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
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Note: This table relates only to the provisions of this instrument as originally made.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 Act.

4 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) overseas regulator; and
- (b) medical device.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

active implantable medical device has the same meaning as in the Regulations.

in vitro diagnostic medical device has the same meaning as in the Regulations.

notified body means a body that has been designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices, including *in vitro* diagnostic medical devices and active implantable medical devices.

recognised auditing organisation means an organisation authorised to perform audits under the Medical Device Single Audit Program by the Regulatory Authority Council, in relation to that program, comprising the Australian Therapeutic Goods Administration, the United States Food and Drug Administration, the Brazilian Agência Nacional de Vigilância Sanitária, Health Canada, and Japan's Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency.

Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

5 Overseas regulators

Each of the following is determined to be an overseas regulator for the purposes of subsection 41BIB(1) of the Act:

- (a) a notified body;
- (b) a recognised auditing organisation;
- (c) Health Canada;
- (d) Japan's Ministry of Health, Labour and Welfare;
- (e) the Japanese Pharmaceuticals and Medical Devices Agency; and
- (f) the United States Food and Drug Administration.