

Therapeutic Goods (Medical Devices) Amendment (Australian Manufacturers) Regulation 2014

Select Legislative Instrument No. 159, 2014

I, General the Honourable Sir Peter Cosgrove AK MC (Ret’d), Governor‑General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation.

Dated 30 October 2014

Peter Cosgrove

Governor‑General

By His Excellency’s Command

Fiona Nash

Assistant Minister for Health

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1 Name

 This is the *Therapeutic Goods (Medical Devices) Amendment (Australian Manufacturers) Regulation 2014*.

2 Commencement

 This instrument commences on 5 November 2014.

3 Authority

 This instrument is made under the *Therapeutic Goods Act 1989.*

4 Schedules

 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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) Regulations 2002

1 Regulation 3.5 (heading)

Repeal the heading, substitute:

3.5 Powers and functions of Secretary in relation to conformity assessment

2 Subregulation 3.5(1)

Omit “that is manufactured outside Australia”.

3 Subregulation 4.1(1)

Repeal the subregulation.

4 Subregulation 4.1(2)

Omit “(2)”.

5 Subregulation 4.1(2)

Omit “and subject to subregulation (3)”.

6 Subregulation 4.1(2)

Omit “manufactured outside Australia”.

7 Subregulation 4.1(3)

Repeal the subregulation.

8 Subparagraph 5.3(1)(j)(viii)

Repeal the subparagraph, substitute:

 (viii) if the Secretary is not satisfied that a body or authority has the authority and expertise to exercise a power or perform a function of the Secretary mentioned in subregulation 3.5(1)—an IVD medical device that has been manufactured in a location and at a site where that body or authority has exercised such a power or performed such a function in relation to the device.