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

OPC60760 - A

Contents

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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