



# Therapeutic Goods (Articles that are Medical Devices) Specification 2014

*Therapeutic Goods Act 1989*

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I, JOHN SKERRITT, delegate of the Secretary of the Department of Health, make this Specification under subsection 41BD(2B) of the *Therapeutic Goods Act 1989*.

Dated December 15, 2014

(Signed by)

**JOHN SKERRITT**  
Delegate of the Secretary of the Department of Health

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**1 Name of Specification**

This Specification is the *Therapeutic Goods (Articles that are Medical Devices) Specification 2014*.

**2 Commencement**

This Specification commences on the day after it is registered.

**3 Articles that are medical devices**

For the purposes of paragraph 41BD(1)(ab) of the *Therapeutic Goods Act 1989*, the following classes of instruments, apparatus, appliances, materials or other articles are specified— instruments, apparatus, appliances, materials or other articles (whether used alone or in combination, and including the software necessary for their proper application) that:

- (a) are intended by the person under whose name they are or are to be supplied to be used for the examination of a specimen derived from a human body for the purpose of:
  - (i) predicting the susceptibility or predisposition of persons to a disease or ailment; or
  - (ii) testing for pregnancy in persons; and
- (b) do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in their function by such means.

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**Note**

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov.au>