



Medical Device Standards Order (Endotoxin Requirements for Medical Devices) 2018

Therapeutic Goods Act 1989

I, Elizabeth McGrath, delegate of the Minister for Health for the purposes of section 41CB of the *Therapeutic Goods Act 1989* and acting under that section, HEREBY DETERMINE:

- (1) that the matters specified in sections 6 and 7 of this Order constitute a medical device standard for the kinds of medical devices identified in section 5 of this Order; and
- (2) that medical devices of those kinds that comply with sections 6 and 7 of this Order are to be treated as complying with Clause 7.2 of the essential principles set out in Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002*, in relation to minimising the risks associated with endotoxin contaminants and residues in or on medical devices.

Dated this 7th day of September 2018

(Signed by)

Elizabeth McGrath

Delegate of the Minister for Health

1 Name of Order

This Order is the *Medical Device Standards Order (Endotoxin Requirements for Medical Devices) 2018*.

2 Commencement

This Order commences on the day after it is registered on the Federal Register of Legislation.

3 Authority

This Order is made under subsection 41CB (1) of the *Therapeutic Goods Act 1989 (the Act)*.

4 Definitions

In this Order:

Act means the *Therapeutic Goods Act 1989*.

default standard has the same meaning as in the Act.

endotoxin is the high molecular weight lipopolysaccharide component of the outer cell wall of gram-negative bacteria, which is usually a fever-inducing contaminant in the manufacturing process of medical devices.

final product medical device or medical device component that has been subjected to all manufacturing processes for the ‘to be marketed’ medical device including packaging and if applicable, sterilisation.

label has the same meaning as in the Act.

manufacturer has the same meaning as in section 41BG of the Act.

medical device has the same meaning as in section 41BD of the Act.

Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*, as in force from time to time.

5 Application

This Order constitutes a medical device standard for any of the following kinds of medical devices:

- (a) implantable medical devices;
- (b) devices in direct or indirect contact with a person’s cardiovascular system, the lymphatic system, or cerebrospinal fluid that are labelled sterile and non-pyrogenic. These include, but are not limited to:
 - fluid pathways of catheters and administration sets such as solution administration sets, extension sets, transfer sets, blood and blood products administration sets, intravenous catheters, extracorporeal

- oxygenator tubing, dialysis tubing, intramuscular drug delivery catheters, transfusion and infusion assemblies, and epidural catheters;
- liquid medical devices such as dialysate; and
 - implantable medical devices such as heart valves, vascular grafts, and cerebral spinal fluid shunt systems;
- (c) devices in direct or indirect contact with a person's intraocular environment. These include but are not limited to:
- intraocular fluids such as ophthalmic viscosurgical devices including viscoelastic surgical aids;
 - implantable intraocular solid devices such as intraocular lenses, implantable miniature telescope, and iris reconstruction lenses;
 - glaucoma devices such as aqueous shunts and intraocular pressure lowering implants;
 - capsular tension ring devices; and
 - accessories of irrigation/aspiration sleeves and tubing used in the intraocular environment; or
- (d) any other devices labelled sterile and non-pyrogenic.

6 Bacterial endotoxin content

- (1) For medical devices other than those mentioned in subsection (2), the endotoxin limits for the final product must be:
- (a) not more than 20 Endotoxin Units per device; or
 - (b) not more than 2.15 Endotoxin Units per device, if the device is in contact with a person's cerebrospinal fluid.
- (2) For medical devices in direct or indirect contact with a person's intraocular environment, the endotoxin limits must unless a higher number of Endotoxin Units is justified be:
- (a) not more than 0.2 Endotoxin Units per device for the anterior segment solid device; and
 - (b) not more than 0.2 Endotoxin Units per Millilitre for the ophthalmic viscosurgical device.
- (3) Where multiple components are assembled into the final product, the cumulative endotoxin content of each individual component must not exceed the overall threshold limit for the final product, as set out in subsections (1) or (2), except where this is justified for a medical device that is included in subsection (2).

7 Bacterial endotoxin testing

- (1) The medical device must be tested using Bacterial Endotoxin Test methodology of a default standard, or if applicable, an alternative method that is validated.
- (2) If an alternative method is used, the manufacturer of the medical device must provide a scientifically sound justification for doing so, and validation evidence for the suitability of the use of that alternative test method in relation to the device.
- (3) Testing must be conducted on every batch, except if this is not practical.
- (4) If testing every batch is not practical, the manufacturer of the medical device must:
- (a) establish an appropriate sampling plan and test for incoming raw materials, in-process materials and representative products to ensure that the manufacturing process is capable of producing every batch of the final

product meeting the endotoxin limits, and provide validation evidence for that sampling plan and test; and

- (b) provide a scientifically sound justification that addresses the risks for not testing every batch.