Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019

I, Miranda Lauman, as delegate of the Minister for Health, make the following order.

Dated 26 March 2019

Miranda Lauman
Assistant Secretary
Medical Devices Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019*.

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**
1. The whole of this instrument	31 March 2019.	31 March 2019

Note: This table relates only to the provisions of this instrument as originally made.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 section 41DC of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) conformity assessment procedures;
(b) kind, in relation to a medical device;
(c) manufacturer, of a medical device; and
(d) medical device.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

ISO means the International Organisation for Standardization.

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

standard means a standard published by the ISO, as in force or existing immediately before the commencement of this instrument.

Note: Standards are published by the ISO at https//www.iso.org.

5 Conformity assessment standards—quality management systems

(1) This section applies in relation to the manufacture of a kind of medical device, whether or not it is intended by the manufacturer to be supplied in a sterile state.

(2) The matters specified in a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 1 to this instrument constitute a conformity assessment standard for a quality management system mentioned in Part 1, 4 or 5 of Schedule 3 to the Regulations.

(3) A quality management system mentioned in Part 1, 4 or 5 of Schedule 3 to the Regulations that complies with a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 1 to this instrument is to be treated as having had applied to it those parts of the conformity assessment procedures specified in column 3 of that item.

6 Conformity assessment standards—quality management systems for kinds of medical devices intended to be supplied in a sterile state

(1) This section applies in relation to the manufacture of a kind of medical device that is intended by the manufacturer to be supplied in a sterile state.

(2) The matters specified in a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 2 to this instrument, when used for a purpose mentioned in column 3 of that item, constitute a conformity assessment standard for a quality management system mentioned in Part 1 or 4 of Schedule 3 to the Regulations.

(3) A quality management system mentioned in Part 1 or 4 of Schedule 3 to the Regulations that complies with a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 2 to this instrument, when that standard is used for the purpose mentioned in column 3 of that item, is to be treated as having had applied to it those parts of the conformity assessment procedures specified in column 4 of that item.

7 Repeals

Each instrument that is specified in Schedule 3 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Conformity assessment standards

Note: See section 5.

Conformity assessment standards for quality management systems		
Column 1	**Column 2**	**Column 3**
Item	**Standard**	**Conformity assessment procedures**
1	ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*	the conformity assessment procedures set out in clause 1.4 of Part 1 of Schedule 3 to the Regulations
2	ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*, other than clause 7.3 *Design and Development*	the conformity assessment procedures set out in clause 4.4 of Part 4 of Schedule 3 to the Regulations
3	ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*, other than: (a) clause 7.3 *Design and Development;* and (b) clause 7.5.6 *Validation of processes for production and services provision*	the conformity assessment procedures set out in clause 5.4 of Part 5 of Schedule 3 to the Regulations

Schedule 2—Conformity assessment standards for medical devices intended to be supplied in a sterile state

Note: See section 6.

Conformity assessment standards for quality management systems for kinds of medical devices intended by their manufacturer to be supplied in a sterile state

Column 1 Item	Column 2 Standard	Column 3 Purpose	Column 4 Conformity assessment procedures
1	both of the following: (a) ISO 11135:2014 *Sterilization of health-care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices*; and (b) ISO 11135:2014/Amd 1:2018 *Revision of Annex E, Single batch release*	for use in the validation and routine control of ethylene oxide sterilization processes for medical devices	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
2	all of the following: (a) ISO 11137-1:2006 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices;* and (b) ISO 11137-1:2006/Amd 1:2013; and (c) ISO 11137-1:2006/Amd 2:2018 *Revision to 4.3.4 and 11.2;* and (d) ISO 11137-2:2013 *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose;* and (e) ISO 11137-3:2017 *Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects of development, validation and routine control;* and	for use in the validation and routine control of radiation sterilization processes for medical devices	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations

Conformity assessment standards for quality management systems for kinds of medical devices intended by their manufacturer to be supplied in a sterile state			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Standard**	**Purpose**	**Conformity assessment procedures**
	(f) ISO/TS 13004:2013 *Sterilization of health care products—Radiation—Substantiation of selected sterilization dose: Method VDmaxSD*		
3	all of the following: (a) ISO 13408-1:2008 *Aseptic processing of health care products—Part 1: General requirements*; and (b) ISO 13408-1:2008/ Amd 1:2013; and (c) ISO 13408-2:2018 *Aseptic processing of health care products—Part 2: Sterilizing filtration;* and (d) ISO 13408-3:2006 *Aseptic processing of health care products—Part 3: Lyophilization;* and (e) ISO 13408-4:2005 *Aseptic processing of health care products—Part 4: Clean-in-place technologies;* and (f) ISO 13408-5:2006 *Aseptic processing of health care products—Part 5: Sterilization in place;* and (g) ISO 13408-6:2005 *Aseptic processing of health care products—Part 6: Isolator systems;* and (h) ISO 13408-6:2005/Amd 1:2013; and (i) ISO 13408-7:2012 *Aseptic processing of health care products—Part 7: Alternative processes for medical devices and combination products*	for use in the validation and routine control of aseptic manufacturing processes for medical devices that are not terminally sterilized, including sterilizing filtration, lyophilisation, clean-in-place technologies, sterilization in place, isolator systems and alternative processes for medical devices and combination products	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
4	ISO 14160:2011 *Sterilization of health care products—Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their*	for use in the validation and routine control of sterilization processes for medical devices	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1

Conformity assessment standards for quality management systems for kinds of medical devices intended by their manufacturer to be supplied in a sterile state			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Standard**	**Purpose**	**Conformity assessment procedures**
	derivatives—Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	using liquid chemical sterilants	of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
5	ISO 14937:2009 *Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*	for use in the validation and routine control of a sterilization process for medical devices that is not mentioned in any of the standards specified in items 1 to 4	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
6	ISO 17664:2017 *Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices*	for use in circumstances where the manufacturer reasonably considers that a medical device is suitable to be cleaned and re-sterilized	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
7	ISO 17665-1:2006 *Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*	for use in the validation and routine control of steam sterilization processes	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment

Conformity assessment standards for quality management systems for kinds of medical devices intended by their manufacturer to be supplied in a sterile state			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Standard**	**Purpose**	**Conformity assessment procedures**
			procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
8	ISO 18362:2016 *Manufacture of cell-based health care products—Control of microbial risks during processing*	for use in the validation and routine control of manufacturing processes used for cell-based health care products that are medical devices	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
9	ISO 20857:2010 *Sterilization of health care products—Dry heat—Requirements for the development, validation and routine control of a sterilization process for medical devices*	for use in the validation and routine control of dry heat sterilization processes	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations
10	ISO 25424:2018 *Sterilization of health care products—Low temperature steam and formaldehyde—Requirements for development, validation and routine control of a sterilization process for medical devices*	for use in the validation and routine control of low temperature steam and formaldehyde sterilization processes	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the

Conformity assessment standards for quality management systems for kinds of medical devices intended by their manufacturer to be supplied in a sterile state			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Standard**	**Purpose**	**Conformity assessment procedures**
			Regulations
11	both of the following: (a) ISO 11607-1:2019 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems;* and (b) ISO 11607-2:2019 *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes*	for use in the validation and routine control of terminally sterilized medical devices	(a) the conformity assessment procedures set out in subparagraph 1.4(5)(d)(i) of Part 1 of Schedule 3 to the Regulations; and (b) the conformity assessment procedures set out in subparagraph 4.4(5)(c)(i) of Part 4 of Schedule 3 to the Regulations

Schedule 3—Repeals

Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008

1 The whole of the instrument

Repeal the instrument.