AS/NZS 4187
RELEVANT STANDARDS

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Relevant Standards

AS 2514	**Drying cabinets** for medical equipment	After the publication of AS/NZS 4187	Manufacturer and Clinical
AS 2774	**Drying cabinets** for respiratory apparatus		Manufacturer and Clinical
AS 2773 AS 2773.1	**Ultrasonic cleaners** for health care facilities Benchtop		Manufacturer and Clinical
AS 2773.2	Non-portable		Manufacturer and Clinical
AS 3789	Textiles for healthcare facilities and institutions		Manufacturer and Clinical

Quality

ISO/DTS 11139:2006	Sterilization of health care products **-** vocabulary		**Manufacturer and Clinical**
ISO 9001	Quality management systems— Requirements	Under review. Due out 2015	Guidance Each HSO have Quality Management System e.g. ACHS
ISO 13485:2003	Medical devices— **Quality management** systems— Requirements for regulatory purposes	Under review 2103	Guidance Each HSO have Quality Management System e.g. ACHS
HB 90.1	The Small Business Handbook—Guide to ISO 9001:2000		Guidance for Quality
ISO 90003	Software engineering— Guidelines for the application of AS/NZS ISO 9001:2000 to computer software		Software engineering— Guidelines for the application of AS/NZS ISO 9001:2000 to computer software

Reprocessing Instructions & W-D

ISO 17664:2004	Sterilization of medical devices—**Information to be provided by the manufacturer** for the processing of re sterilizable medical devices	Under revision 2013 -2015	Manufacturer and Clinical
ISO 15883-1: 2006 Confirmed 2009	**General requirements**, terms and definitions and tests	Amd1 2014 under systematic review	This part of ISO 15883 may be used by **prospective purchasers and manufacturers** as the basis of agreement on the specification of a WD. The test methods for demonstration of compliance with the requirements of this part of ISO 15883 may also be employed by users to demonstrate continued compliance of the installed WD throughout its working life. Guidance on a routine test programme is given in Annex A.

Washer Disinfectors

ISO 15883-2: 2006 Confirmed 2010	Requirements and tests for **washer-disinfectors employing thermal disinfection** for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	Due 2015	**Manufacturer and Clinical** In conjunction with ISO 15883.1 Manufacturer RMD compatible, inner and outer surfaces, lumen. Chemicals reference back to ISO 15883-1:2006, 5.7.2, 5.7.4 and 5.7.5 4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1:2006 using the test soils and methods specified in ISO/TS 15883-5 that are pertinent to the loads to be processed 4.3.1 Each operating cycle shall include a thermal disinfection stage for which the time at which the load is maintained at the disinfection temperature gives an *A*0 of at least 600 on all surfaces of the load … 6.3.2.1 The test loads specified below are reference loads which shall be used for type tests and may be used for works test or operational qualification test 7. Information to be supplied by the manufacturer

Washer Disinfectors

ISO 15883-3: 2006 Confirmed 2010	Requirements and tests for washer-disinfectors employing **thermal disinfection for human waste containers**	Due 2014	**Relevant Manufacturer and clinical**
ISO 15883-4: 2008 Confirmed 2011	Requirements and tests for washer-disinfectors employing **chemical disinfection for thermolabile endoscopes**	Under revision 2014 at Committee stage	**Relevant Manufacturer and clinical**
ISOTS 15883-5: 2005 Confirmed 2009	Test soils and methods for demonstrating **cleaning efficacy**	Review in progress 2014	**Manufacturer and Clinical**
ISO 15883-6: 2011	Requirements and tests for washer-disinfectors **employing thermal disinfection for non-invasive**, non-critical medical devices and healthcare equipment	Published	**Relevant Manufacturer and clinical**

ISO 11607 **Packaging** for terminally sterilized medical devices

ISO 11607-1:2013	Part 1: **Requirements for materials**, sterile barrier systems and packaging systems	Amd 1:2014	**Manufacturer and Clinical** specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering the wide range of potential materials, medical devices, packaging system designs, and sterilization methods harmonized with EN 868-1 and specifies general requirements for all packaging materials whereas EN 868 Parts 2 to 10 specify particular requirements for a range of commonly used materials

ISO 11607 **Packaging** for terminally sterilized medical devices

ISO 11607-2:2013	**Validation requirements** for forming, sealing and assembly processes	Confirmed for review	**Manufacturer and clinical** the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.
ISODTS 16775:2014	Packaging for terminally sterilized medical devices— **Guidance on the application** of ISO 11607-1 and ISO 11607-2	Published	**Manufacturer and Clinical**

Chemical & Biological Indicators

ISO 11140: 2005	Sterilization of health care products—**Chemical indicators** (series)	Part 1 due 2014. Parts 3-5 due 2015. Part 6 under development	manufacturer standards and are not intended for use by end users
ISO 15882: 2008	Sterilization of health care products —**Chemical indicators — Guidance** for selection, use and interpretation of results	Confirmed for review 2014	intended for use by end users
ISO 11138	Sterilization of health care products—**Biological indicators** (series)	New project approved to be reviewed 2014	manufacturer standards and are not intended for use by end users
ISO 14161: 2009	Sterilization of health care products — **Biological indicators — Guidance** for the selection, use and interpretation of results	To be reviewed 2014	intended for use by end users

Other Biological Indicator

ISO 11737: 2006	Sterilization of medical devices—Microbiological methods	In review stage	In case you want to define own sterilising process, inoculate products and recover microbes
ISO 11737-1	Determination of a population of microorganisms on products	In review stage	
ISO 10993	Biological evaluation of medical devices		The standards on microbial testing and biocompatibility/ biological evaluation etc would only be used if an HSO was going to undertaken processes outside of those supplied by the steriliser equipment manufacturer.

ISO 17665 Sterilization of health care products—

Moist heat

ISO 17665-1: 2006	Requirements for **the development, validation and routine control** of a sterilization process for medical devices	Confirmed review Due 2015	**Manufacturing a steriliser e.g. ISO 17665.1 A12**
ISOTS 17665-2: 2014	**Guidance** on the application of ISO 17665-1	Published	**Clinical** – Routine monitoring, maintaining process effectiveness
ISOTS 17665-3:2013	Guidance on the **designation of a medical device to a product family** and processing category for steam sterilization	Published	**Clinical** – Routine monitoring, maintaining process effectiveness
EN 285:2006+A2:2009	Sterilization—Steam Sterilizers—Large Sterilizers	Exp March 2010 for purpose of declaration of conformity	**Manufacturer**

Small Moist Heat sterilisers

EN 13060:2004+A2: 2010	**Small Steam** Sterilizers	Exp Sep 2010 for purpose of declaration of conformity	**Manufacturer & Clinical**
EN 867-5:2001	Specification For Indicator Systems and Process Challenge Devices For Use in Performance Testing For **Small Sterilizers Of Type B and Type S** Note: EN 867 and 867-5 are expected to be superseded by ISO 11140-6 (in preparation		**Manufacturer**

Low Temperature Sterilisers

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	Under review 2103	**Manufacturer and Clinical** Applied to any sterilisation process for which no other standard applies - e.g. low temperature sterilisation process
ISO 25424: 2009	Sterilization of medical devices—**Low temperature steam and formaldehyde**—Requirements for development, validation and routine control of a sterilization process for medical devices	To be reviewed	**Manufacturer and clinical**
EN 14180	Sterilizers for Medical Purposes—**Low Temperature Steam Formaldehyde Sterilizers**—Requirements and Testing		**Manufacturer and clinical**

Ethylene oxide

ISO 10993-7	Ethylene oxide sterilization residuals	Due 2013	
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	Published	

Dry Heat

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	Review 2015	**Manufacturer and clinical**

Building

HB 260	Hospital acquired infections— **Engineering** down the risk, Standards Australia		Building
AS 2896	**Medical gas systems** - installation and testing of non-flammable medical gas pipeline systems.		Medical gas systems and fire / smoke systems are an engineering thing and they would be responsible for this rather than a CSSD person.

AS1668 The use of **ventilation and airconditioning** in buildings

AS1668.1	**Fire and smoke** control in multi-compartment buildings		Medical gas systems and fire / smoke systems are an engineering thing and they would be responsible for this rather than a CSSD person
AS1668.2	**Ventilation** design for indoor air contaminant control		Ventilation standards would be used when ensuring your HEPA filters, air change rates and pressure differentials are in accordance with specification – i.e. once a year.
AS1668.3	**Smoke control** systems for large single compartments or smoke reservoirs		Medical gas systems and fire / smoke systems are an engineering thing and they would be responsible for this rather than a CSSD person

Legend

- **Legend**
- ISO – International Standards Organisation
- ISO TS – International Standards Organisation Technical Specification – usually a guidance document
- EN – European Norm
- AS – Australian Standard
- AS/NZS – Australian New Zealand Standard
- HB – Handbook

ISO Standards development

ISO Standards development goes through the following stages (each stage has a different time frame for the ballot):

- NWIP (New Work Item Proposal), a draft document which is balloted prior to be accepted;
- WD (Working Draft) discussed and developed within the committee (no ballot);
- CD (Committee Draft) , goes out to committee and their nominating organisations for comment- comments from each member country are then returned to secretary. Committee meet to discuss and resolve comments,
- DIS (Draft International Standard) again goes out to committee and comments returned to secretary – comments discussed and resolved (member country ballot),
- FDIS (Final Draft International Standard) (ballot). At the FDIS stage, there can only be editorial changes - no technical ones.