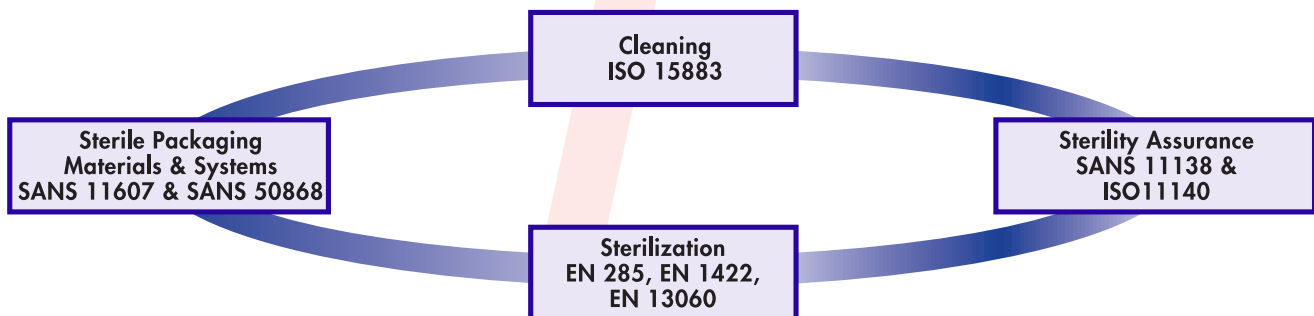


## Standards are living documents that need to be updated periodically to keep abreast of the current state of knowledge

Standards are needed for the uniform designation, design and testing of products and services used in the healthcare industry, as well as in the general economy. In principle there is only one valid standard governing any one fact. It can be presumed that a standard will take account of the current stock of knowledge as well as of experiences relating to the period predating publication of the standard, but this situation changes over time. Many standards are being applied as a matter of course so that it is often forgotten that sometimes standards have to be amended to keep abreast of the current state of knowledge.

There is also a general trend throughout the World to harmonize individual country (e.g. BS, DIN, AFNOR) and regional standards (e.g. EN) to International (ISO) standards. This process is a lengthy one and is far from complete. The harmonisation process to ISO standards generally entails getting International agreement on Part 1 of the standard as a first phase. Part 1 is referred to as the Horizontal standard and this covers the General Requirements of the standard. The Vertical standards (Parts 2, 3 etc) are then reviewed as a second phase. Standards South Africa (SABS) has also started a process of adopting such International standards as well as revising their own standards.

Below is an update on the current status of the ISO, European and South African standards that have been published to guide hospitals in developing a Total Quality Management system for the sterile processing of their medical devices. These standards give detailed specifications and performance criteria for the materials, equipment and processes that they cover and the purpose of this review is to summarise the important aspects of each one.



### CLEANING

Washer – Disinfectors ISO 15883-1 : 2006 General Requirements		
ISO 15883-2	ISO 15883-3	ISO 15883-4
Thermal disinfection for surgical instruments, anaesthetic equipment etc	Thermal disinfection for human waste containers	Chemical disinfection for thermo-labile endoscopes

This ISO standard, which was published in 2006, specifies general performance requirements for washer-disinfectors and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It encompasses 4 parts as can be seen from the accompanying diagram. The first part ISO 15883-1 is a general requirement and is known as the horizontal standard. Parts 2 - 4, which are known as the vertical standards, apply to the specific types of cleaning processes and must be read in conjunction with Part 1.

#### Performance requirements in Part 1 include:

- General (automatic cycle control, criteria for disinfection etc.)
- Cleaning (definition of test soils, temperature during the flushing and washing stage)
- Disinfection (thermal and chemical disinfection, rinsing, drying)
- Process Chemicals
- Mechanical and Process requirements
- Testing for Conformity

#### Washer-Disinfectors for Surgical Instruments

ISO 15883-2 specifies the particular performance requirements for washer-disinfectors that are intended to be used for cleaning and chemical disinfection of surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. Performance Requirements covered in this standard include cleaning and disinfecting efficacy and the monitoring the temperature on internal surfaces of devices. Also included are mechanical and control requirements and the methods of testing for conformity to the standard.

## STERILE PACKAGING MATERIALS & SYSTEMS

Sterile Packaging Materials & Systems SANS 11607-1: 2006 / ISO 11607-1: 2006 General Requirements						
SANS 50868-2	SANS 50868-3	SANS 50868-4	SANS 50868-5	SANS 50868-6	SANS 50868-7	SANS 50868-8
Sterilization Wrap	Paper for use in Bags & Reels	Sterilization Bags	Heat & Self-sealable Pouches & Reels	Paper for EO or Irradiation sterilization	Adhesive coated paper	Re-usable containers

South Africa adopted the European standard EN 868 in its entirety during 2003 and it has been re-numbered SANS 50868 by Standards South Africa. Part 1 of the European standard was further harmonised to become an ISO standard in 2006 and South Africa has also adopted this standard. The standard encompasses 8 parts as can be seen from the accompanying diagram. The horizontal standard SANS 11607-1 is the general requirement and the vertical standards 2 - 8 apply to the specific types of packaging. All packaging products need to comply with Part 1 and also the specific vertical standard relevant to them.

### The General Requirements for Part 1 are: -

- Compatibility with the medical device
- Compatibility with the method of sterilization
- Compatibility with the labelling system
- Toxicity
- Microbial Barrier

### Shelf Life

The standard states that it is the manufacturer's responsibility to provide documentation, to confirm the compatibility of the packaging system, with the medical device, method of sterilization and labelling system. The manufacturer must also provide information on toxicity and also most importantly, supply certification for a recognised international barrier test such as DIN 58953 Part 6, BS 6256: 1989 or ASTM F 1608 Bacterial Filtration Efficiency Test. Proof must also be provided on shelf life, as such, manufacturers must give a period of time that the pack will remain sterile, given specific circumstances. The standard also points out that the maintenance of sterility is event related rather than time related and many factors may affect this, such as the level of micro-organisms in the environment and the size of particles on which they occur. The first part of the standard relies very much on information supplied by the manufacturer; parts 2 - 8 assure the physical characteristics of the product.

### Specific Requirements for Sterilization Wrap SANS 50868-2:2003

The standard details the physical characteristics necessary for Plain paper, Crepe paper, and Non-wovens (which include linen, barrier fabrics, paper/synthetic blends or wholly synthetic materials). These requirements can be categorized as follows: -- Strength (Tear, burst, tensile and stretch)- Barrier (Air Permeance, water repellency, pore size and surface absorbency)  
- Drapeability

## STERILIZERS

Sterilizers		
EN 285:2006	EN 1422:1997	EN 13060:2004
Large Steam Sterilizers	Ethylene Oxide Sterilizers	Small Steam Sterilizers

The above three standards regulate the most common methods of sterilization carried out in hospitals.

### Large Steam Sterilizers

The European standard EN 285:2006 specifies requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of wrapped goods such as porous loads and instruments. This European standard is not applicable to small sterilizers, having a chamber volume of less than 60 litres, and also does not describe a quality assurance system for the control of all stages of manufacture of the sterilizer. Attention is drawn to the standards for quality management systems e.g. ISO 13485:2003 in this regard.

It should be noted that where sterilization wrap is intended for use as a sterile field, where contact with low surface tension liquids can occur, the repellency to low surface tension liquids shall be not less than 7 when tested in accordance Annex A.

### Specific Requirements for Paper Bags SANS 50868-4:2003

This part of the standard provides particular requirements and test methods for paper bags that are suitable for use as packaging of medical devices that are to be terminally sterilized. The requirements in this part of the standard include:

- Bottom and back seal construction
- Process indicator system
- Performance requirements of bag
- Marking of bags

Manufacturers must also demonstrate that they utilize single web paper specified in SANS 50868-3:2003. In South Africa, Sterilization Bags are manufactured to comply with the SANS standard CKS 595:1984 (*Paper Bags for Steam Sterilizing - Medical*). This is obviously a much older standard but it still incorporates many of the requirements of EN 868 as this standard was derived from British and other similar standards.

### Specific Requirements for Heat & Self-Sealable Pouches & Reels SANS 50868-5:2003

This part of the standard provides particular requirements and test methods for heat and self-sealable pouches as well as reels manufactured from paper complying with SANS 50868-3:2003 and plastic film complying with Clause 4 of SANS 50868-5:2003. The requirements in this part of the standard include:

- Manufacture from a single web paper specified in SANS 50868-3:2003
- Specification of plastic film
- Construction and design
- Process indicator system
- Performance requirements and test methods
- Marking of pouches and reels

### The standard covers amongst others, the following aspects of design and performance:

- Mechanical components (materials, door design, test connections, insulating material, framework and panelling)
- Process components (pipework and fittings, steam generators, air filters, vacuum system)
- Minimum Required Instrumentation (chamber temperature indicators and recorders, chamber pressure indicators and recorders, jacket pressure indicating instrument, steam pressure gauge, sterilization cycle stage indicator, cycle counter)
- Control systems (automatic controller with pre-set cycles including Bowie-Dick cycle if sterilizer operates with a plateau period in excess of 3.5 minutes)
- Performance requirements (microbial efficacy, physical parameters, air removal and steam penetration, load dryness)
- Test programmes (microbiological, thermometric, air leakage, air detection, load dryness, steam quality)

# STERILITY ASSURANCE STANDARDS

Sterility Assurance Standards		
SANS 11138:2007 / ISO 11138:2006	ISO 11140- 4	ISO 11140-1
Biological Indicators	Bowie-Dick Tests	Chemical Indicators

## Biological Systems for Testing Sterilizers

Biological Indicators SANS 11138-1:2007 / ISO 11138-1:2006 - General Requirements			
SANS 11138-2	SANS 11138-3	SANS 11138-4	SANS 11138-5
Biological Indicators for Ethylene Oxide sterilization	Biological Indicators for moist heat sterilization	Biological Indicators for dry heat sterilization	Biological Indicators for low temperature steam & formaldehyde sterilization

Standards South Africa adopted the ISO 11138 standard in 2007. This standard, which replaced the European standard EN 866 in its entirety, encompasses 5 parts as can be seen from the accompanying diagram. The horizontal standard SANS 11138-1 is a general requirement and the vertical standards 2 - 5 apply to the specific types of sterilization process or type of indicator. The particular vertical standards need to be read in conjunction with the horizontal standard.

## Chemical Indicators & Bowie-Dick Tests

ISO 11140-1: 2005 - General Requirements				
ISO 11140-2	ISO 11140-3	ISO 11140-4	ISO 11140-5	ISO 11140-6
Relevant test methods and equipment	Class 2 indicator systems for use in the Bowie & Dick-type steam penetration test	Class 2 indicators as an alternative to the Bowie & Dick-type test for detection of steam penetration	Class 2 indicators for Bowie & Dick-type air removal tests	Class 2 indicators and process challenge devices for use in performance testing for small steam sterilizers

The ISO standard 11140 is in the process of being revised and when the work is complete, it will consist of 6 parts as indicated above. The purpose of this work is to harmonize the European standard EN 867 with the ISO standard, so that there will only be one standard for Chemical Indicators.

Parts 1 and 2 of EN 867 have already been replaced with ISO 11140 -1. Parts 3 and 4 of EN 867 are currently in the 6 month transition period to the new ISO ones, and will be adopted within the next few months. Parts 3 and 4 are virtually identical, bar a few 'editorial' changes.

Part 5 contains both the alternative and the test sheet in the same standard (i.e. same scope as 3 and 4), yet the performance of all of part 5 is geared to the lower sensitivity US market. So there are two standards for the same products.

EN 867 Part 5 for small sterilizers is currently under review and will become ISO 11140 Part 6

**Alternative Indicators for the Bowie & Dick Test**  
ISO 11140-4 which has replaced EN 867-4 is an important standard for the CSSD in view of the fact that predominantly alternative indicators are used for the daily Bowie & Dick test. Alternative indicators for the Bowie and Dick Test, consist of the indicator system and a test load, which can be used either once or on several occasions. It should be noted that based on ISO 11140-4, an indicator system is the combination of the indicator reagent and its substrate. Thus a test sheet for the Bowie & Dick test is an indicator system and only in conjunction with the test pack does it become an indicator for the Bowie & Dick test. It is the performance of the ready-to-use indicator that is checked for compliance.

## Compliance with ISO 11140-4

In order to show that an alternative to the original Bowie Dick Test pack conforms to ISO 11140-4, a manufacturer must demonstrate amongst other criteria that:

- The pack exhibits the properties of the original towel pack
- The pack has been tested in over 400 cycles
- A 2°C temperature depression can be detected between the centre of the pack and the chamber drain of the autoclave
- There is no transfer of ink from the indicator sheet
- There is clear labelling

A key requirement of this standard is the ability to detect a 2°C temperature depression in the centre of the pack. The 2°C temperature depression is the difference in temperature between the centre of the pack and the sterilizer drain (the coldest part of the chamber). It represents the presence of air or non-condensable gases and a pack that meets the ISO 11140-4 requirements gives the end user a high level of security. The test methods referred to in these standards require specialised equipment that not many independent test laboratories possess. The SABS does not have the equipment required to evaluate Bowie-Dick tests and Chemical Indicators. The British Standards Institute (BSI) is however, capable of testing these products and should a manufacturer's product be found to comply with the relevant parts of ISO 11140, they will issue a Kitemark to this effect.

The Kitemark implies that the product conforms to the required standard and that it will be subjected to ongoing testing to ensure that it continues to do so in the future. The Kitemark is the world's premier symbol of trust, integrity and quality. Manufacturers having this associated with their product or service will reassure customers and specifiers alike that they have satisfied the most rigorous of quality processes

## Chemical Indicator Standards

In addition to containing information on the General Requirements of the standard, ISO 11140-1 also contains information on the classification and performance requirements of the various classes of chemical indicators. The critical process variables for each type of sterilization process are also defined. This can be of great assistance in helping hospital personnel to select the correct indicator for a specific purpose. This part of the standard defines the various classes of indicators as shown below:-

### Class 1: Process indicators

Process indicators are intended for use with individual units, (e.g. Packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. The endpoint indicating exposure to a steam sterilization process shall not occur until the indicator has been exposed to saturated steam for not less than 3 minutes at 121-124°C, or for 30 seconds at 134 - 137°C. (An example of a Class 1 indicator is autoclave tape)

### Class 2: Indicators for use in specific tests

These indicators are designed for use in specific test procedures as defined in relevant sterilizer/sterilization standards. (An example of a Class 2 indicator is a Bowie-Dick test)

### Class 3: Single variable indicators

A single variable indicator shall be designed for one of the critical variables to be monitored. This could be time, saturated steam or temperature in the case of a steam sterilization cycle.

### Class 4: Multi-variable indicators

A multi-variable indicator shall be designed for two or more of the critical variables which affect the efficacy of the sterilization process to be monitored and shall indicate exposure to a sterilization cycle at stated values of the chosen variables. Multi-variable indicators shall undergo a clearly detectable change indicating exposure to the sterilization cycle at defined variables within the relevant tolerances listed in Table 1. The defined variables and the stated values at which the indicator reaches its endpoint shall be identified or coded on the indicator. (An example of a Class 4 indicator is the Browne™ MVI Steam Indicator strip)

**TABLE 1: TOLERANCES & LIMITING VALUES FOR RESPONSE TO CRITICAL PARAMETERS FOR STEAM INDICATORS**

Indicator Class	Time (Minutes) Limiting Values		Temperature ° C Limiting Values		Steam Saturation Limiting Values	
	Lower	Upper	Lower	Upper	Lower	Upper
4	-25 %	0 %	-2	0	0.85	1.00
5	-15 %	0 %	-1	0	0.85	1.00
6	-6 %	0 %	-1	0	0.85	1.00

**Class 5: Integrating indicators**

Integrating indicators are indicators designed to respond in a similar manner to that of a Biological Indicator when exposed to all critical variables of a sterilization process. The exposure required to effect the change in the indicator shall be related to the inactivation of a theoretical micro-organism of stated D or z values. These values shall be equivalent to or exceed the performance specified in the appropriate parts of ISO 11138 for biological indicators for use in routine monitoring of the relevant sterilization process. The theoretical inactivation of the micro-organism shall be stated as the fractional reduction in the population expressed as the log10. Integrating indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle at defined variables within the relevant

tolerances given in Table 1. The stated values should be identified or coded on the product. (An example of a Class 5 indicator is the Verify™ Steam Integrator)

**Class 6: Emulating indicators (Cycle Verification indicators)**  
Emulating indicators are indicators designed to react to all critical variables over a specified range of sterilization cycles, for which the stated values are based on the settings of the selected sterilization cycles. Emulating indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle at defined variables within the relevant tolerances given in Table 1. The stated values shall be identified or coded on the product. (An example of a Class 6 indicator is the Browne™ TST Control)

# notice board

## Sterilization and Decontamination Courses for 2008

SafMed is proud to be associated with the above training courses offered by Stellenbosch University (SU). It is a requirement that candidates must have successfully completed the Foundation Course in Sterilization and Decontamination in order to be accepted onto the SU courses. SafMed will once again be sponsoring the Foundation Courses in 2008.

**Entry Requirement for Sterilization and Decontamination Courses**

- Grade 10 certificate or equivalent - At least 2 years experience in a CSSD
- Competence must be achieved in Foundation Course to attend Basic Course
- Competence must be achieved in Basic Course to attend Intermediate Course
- Competence must be achieved in Intermediate course to attend Advanced Course.

Course	Provisional Cost per module	Qualification
Foundation	Free – Sponsored by SafMed	Certificate Competence SafMed
Basic	R3,000.00 (R2,500.00 Tygerberg)	Cert. Competence Stellenbosch University
Intermediate	R5,000.00	Cert. Competence Stellenbosch University
Advanced	R5,000.00	Cert. Competence Stellenbosch University

Below is a list of Training Courses that have been scheduled for the year.

Course	Venue	Provisional date	Deadlines for Applications
Foundation Course in Sterilization and Decontamination	Cape Town	24 January 2008	10 January 2008
Basic Course in Sterilization and Decontamination	Tygerberg	4 Feb – 8 Feb 2008	7 January 2008
Foundation Course in Sterilization and Decontamination	Bloemfontein	19 Feb 2008	5 Feb 2008
Foundation Course in Sterilization and Decontamination	Gauteng	21Feb 2008	7 Feb 2008
Foundation Course in Sterilization and Decontamination	Eastern Cape	13 March 2008	29 Feb 2008
Basic Course in Sterilization and Decontamination	Tygerberg	14 – 18 April 2008	24 March 2008
Foundation Course in Sterilization and Decontamination	Gauteng/NW	8 May 2008	25 April 2008
Basic Course in Sterilization and Decontamination	Gauteng	19 – 23 May 2008	5 May 2008
Intermediate Course in Sterile Services	Tygerberg	23 June – 4 July 2008	12 May 2008
Foundation Course in Sterilization and Decontamination	Mpumalanga	7 August 2008	24 July 2008
Basic Course in Sterilization and Decontamination	KwaZulu	8 – 12 Sept 2008	25 August 2008
Basic Course in Sterilization and Decontamination	Namibia	29 Sept – 3 Oct 2008	15 Sept 2008
Advanced Course in Sterile Services	Tygerberg	20 – 31October 2008	1 Sept 2008

**For further information and application forms all Courses please contact:**

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