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Standards & News: Chemical Indicators

Jan Oort , Sales Director

INTERSTER INTERNATIONAL BV
Samsonweg 2, 1521 RC Wormerveer, The Netherlands
T: +31 (0)75 627 22 22
F: +31 (0)75 627 22 00
info@interster.nl
www.interster.nl

TOP 1: Chemical Indicators

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EN ISO 11140 Series: Part 1 (2015)

News

Former “Class” → **Now “Type”**

Type 1 to **Type 6** have different applications and give different information, rather than having a hierarchy.

Category concept (→ according to the intended use): **e1**(exposure); **s2** (special); **i3** (internal); **i4**; **i5**; **i6**

A **C**hemical **I**ndicator (**CI**) is able to provide information.

What kind of information?

EN ISO 11140 Series: Part 1

Type 1:

Process indicator (STEAM, DRY; EO; FORM; VH_2O_2; IRRAD):

Demonstrates:

Item exposed to a sterilization process

→ **COLOR CHANGE**

or not → **NO COLOR CHANGE**.

NOTE: Current requirements for the reaction pattern of **Type 1** STEAM **CI** are less demanding compared to the old standard for Class 1.

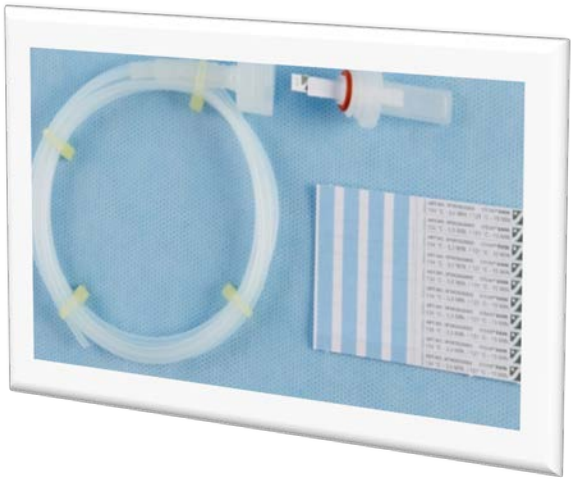
Type 1 for safe Logistics in CSSD

In a CSSD process, exposed MDs have to be distinguished from non-process exposed.

The **Type 1 CI** covers this requirement in a simple and safe way.

Type 1 gives no information about the quality of the sterilization process.

EN ISO 11140 Series: Part 3, 4, 5



Type 2:

CI for special Tests in **STEAM**

Demonstrates:

Steam penetration of the process was sufficient →**PASS** or not → **FAIL**.

Application:

Routine control (B&D Test; “Helix Test”)

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Type 2: Sterilization needs Transport of sterilizing agent

Every surface within the load at all locations shall be reached by the sterilizing agent:

→ **Sufficient Penetration**

To be demonstrated in routine control e.g. via B&D - Test, “Helix - Test”

Type 2: The Bowie & Dick Test

The B&D test is a daily routine control test for the STEAM sterilizer.

All air within the B&D Test device must be replaced by STEAM.

A standard compliant B&D's STEAM penetration barrier is equal to a 7 kg towel pack (= standard reference).

Type 2: The Bowie & Dick Test

B&D test in the morning → **PASS** → the sterilizer is **ready for use** for the rest of the day!

The machine's process provides a fast and even air removal and STEAM penetration!

FAIL → Poor steam penetration into the B&D as a result of too much non condensable gases (= air, CO_2, etc.) in the test environment.

Type 2: The Helix Test

At the moment there is no specific standard for a "Helix Test" in a Load.

EN 867-5 is a standard for a type test device (= "Helix") to be used for type testing of small STEAM sterilizers.

EN 867-5 is widely accepted as a standard reference for the "Helix Test".

ISO TC 198 WG 6 and CEN TC 102 WG 7 try to joint harmonize EN 867-5 to "**EN ISO 11140-6"!**

Type 2: The Helix Test

EN 285

Sterilization - Steam sterilizers - Large sterilizers

3.25 Process challenge device PCD

Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

3.40 Type test

Series of checks and tests for a particular design of sterilizer to demonstrate compliance with the requirements of this European Standard.

Type 2: The Helix Test

15.1 General

The hollow load test is used to demonstrate that at the levels at which the controls are set, air removal from within the test piece is sufficient to permit even steam penetration into it. The test is performed using the process challenge device unwrapped.

Type 2: Helix Test Pass / Fail

PASS → Full STEAM penetration **=** Indicator strip has enough steam detected.

A PASS result may be one element of an overall sterility assurance programme.

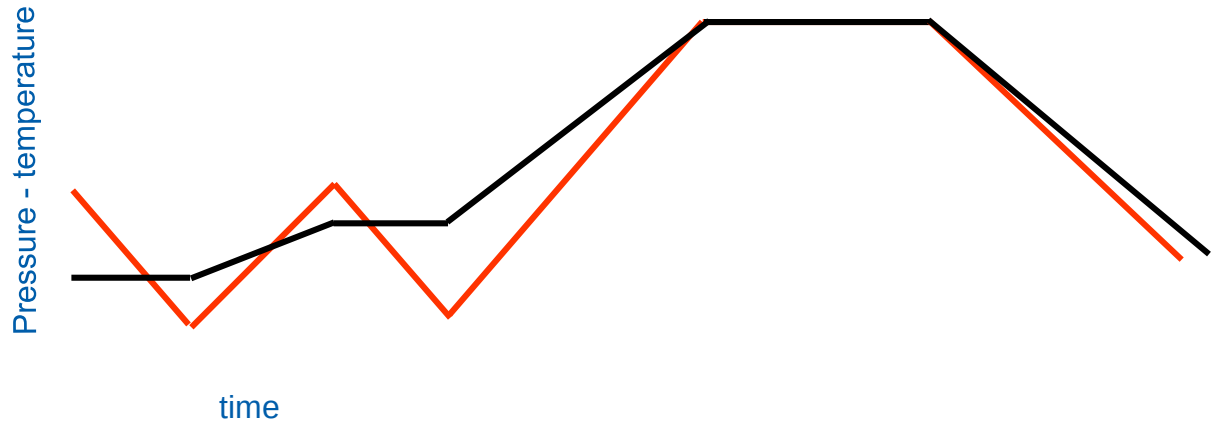
FAIL → Poor STEAM penetration = Indicator has to less or no steam detected.

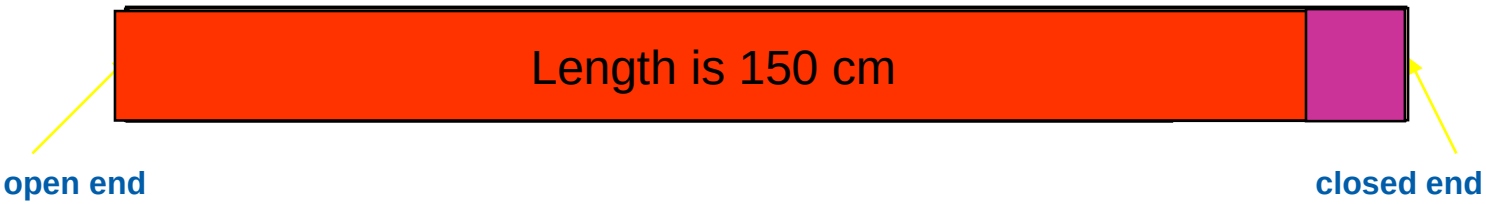
A FAIL result means: no release of the MDs without investigation into the cause or causes.

For a good result of the Helix Test, we need: convection, diffusion, condensation and time.

Pressure = red line

Temperature = black line





EN ISO 11140 Series: Part 1 New!

Type 3 to 6

STEAM; DRY; EO; FORM; VH_2O_2; demonstrates reach of **Stated Values SV** for **C**ritical **P**rocess **V**ariables **CPV** (time, temperature, gas conc., etc.) → **PASS** No reach → **FAIL**; Application: Routine control

Type 3: “Single variable”;

Type 4: „Multivariable“

Type 5: „Integrator“ match a **biological indicator**

Type 6: „Emulator“ **all** variables reached stated values

Type 3, 4, 5, 6: Sterilization needs CPV

CPV for **STEAM** Sterilization are:

→ Time
→ Temperature
→ Steam

For a successful sterilization all of these variables must be achieved:

→ **Minimum Values**

Compare of Test Points: STEAM Type 3 & 4, 5, 6

	Type 3 & 4	Type 5	Type 6
PASS	SV	SV	SV
FAIL	- 2°C - 25% Time	- 1°C - 15% Time	- 1°C - 6% Time

"No information" Area of Type 3 & 4 > Type 5 > Type 6

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Currently existing types of CI for sterilization processes

Type	STEAM	DRY	EO	IRRAD	FORM	VH2O2
1						
2						
3						NEW
4						NEW
5						
6						

Summary

Chemical Indicators are **very important means** for:

- → Distinguish between **Processed** and **Non Processed** MDs.
- → Check of the **STEAM penetration characteristics** of the sterilizer's performance on a routine basis (B&D; Helix Test)
- → Give valuable information of **Stated Values** of **CPV** reached on location in the load.

TOP 2: Medical Packaging

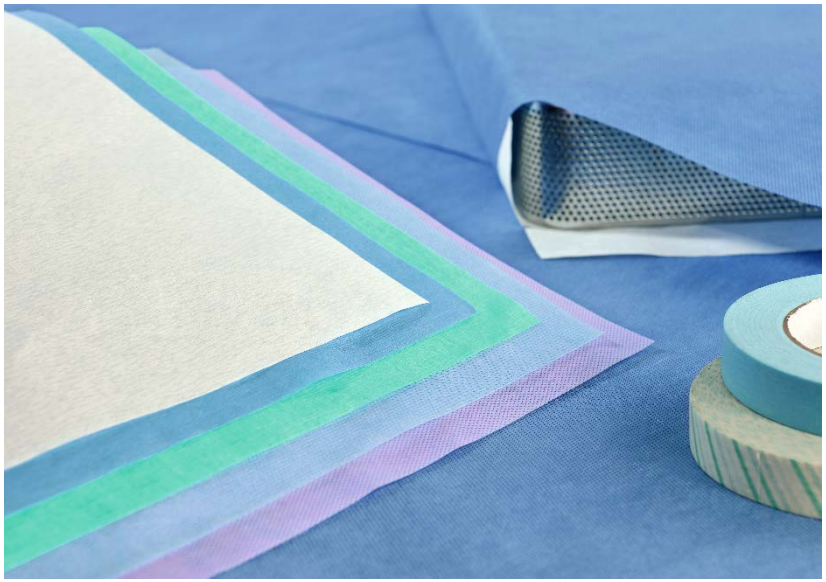
Standards:

ISO 11607 Series;

EN 868 Series;

CEN ISO/TS 16775;

EN 868 Series Parts 2, 3, 4, 6, 7
under revision



Important Test methods in EN 868 series, i.e. for:

Pore size

Water repellency

Chloride content

Sulfate content

have been updated by Round Robin Testing. Now have a statement of **reproducibility** and **repeatability**, to be implemented in EN ISO 11607-1's list of test methods.

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EN 868 Series Parts 2, 3, 4, 6, 7
under revision

Two more test methods in EN 868 series, i.e. for

seal strength

fluorescence

have been revised.

Statements have been implemented concerning the regulatory significance EN 868 vs. EN ISO 11607 in Europe.

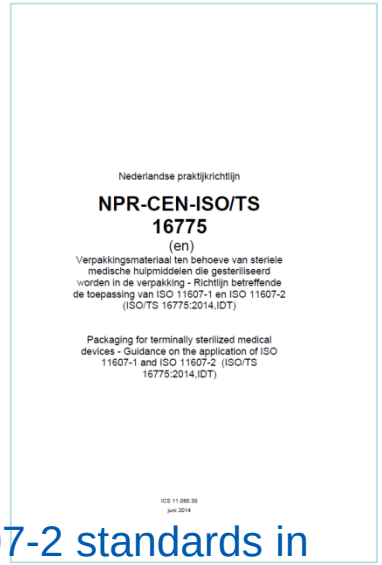
EN ISO 11607 Series

A decision on revision of EN ISO 11607 series is expected in early fall 2016, too. Works may start in December this year in Berlin.

If to be revised, focus might be on:

- microbial barrier test methods
- other test methods (Annex B)
- regulatory issues (e.g. Annex ZA), etc.

NEW NRP-CEN-ISO/TS 16775


Nederlandse praktijkrichtlijn

NPR-CEN-ISO/TS 16775

(en)

Verpakkingsmateriaal ten behoeve van steriele medische hulpmiddelen die gesteriliseerd worden in de verpakking - Richtlijn betreffende de toepassing van ISO 11607-1 en ISO 11607-2 (ISO/TS 16775:2014,IDT)

Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO/TS 16775:2014,IDT)

ICS 11.080.30

juni 2014

Name of the standard:

- TS 16775: Packaging for terminally sterilized medical devices – Guidance on application of ISO11607-1 and ISO11607-2

Goal of the standard:

- Describing how to use and implement the ISO11607-1 and ISO11607-2 standards in healthcare facilities and manufacturers of medical devices

Important points / requirements:

- Article 3: Explanation for the end-user (hospitals, clinic's ect.)
- Article 4: Explanation for the manufacturer (Interster and YOU)
- Annex A till S!: Extra information

Remark:

- Brand new standard that was introduced in 2014! A must to read!

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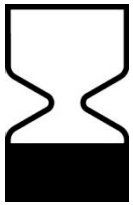
Medical devices symbols

LOT

REF



STERILE EO

NON STERILE

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Symbols for medical devices

Name of the standard:

- ISO 15223-1 and ISO15223-2 Symbols to be used with medical device for labeling

Goal of the standard:

- Describing which symbols the manufacturer of medical devices should provide to the end-user

What's new?:

- The ISO 15223-1 series replaced the European standard EN 980 in 2013!
- The ISO 15223-1 includes most of the EN 980 symbols, with the exception of the Latex free symbol! The ISO 15223-1 does not use 'negative' symbols, with the exception of 'do not resterilize' and 'do not re-use'.
- The ISO 15223-2 explains how you can design your own symbols and how to supply them to the symbol comity.

Thank you! –

Questions welcome …