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Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

Harmonised standards? The MDR and Brexit era – a brief update of ISO/TC 198's standards and associated activities

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Overview

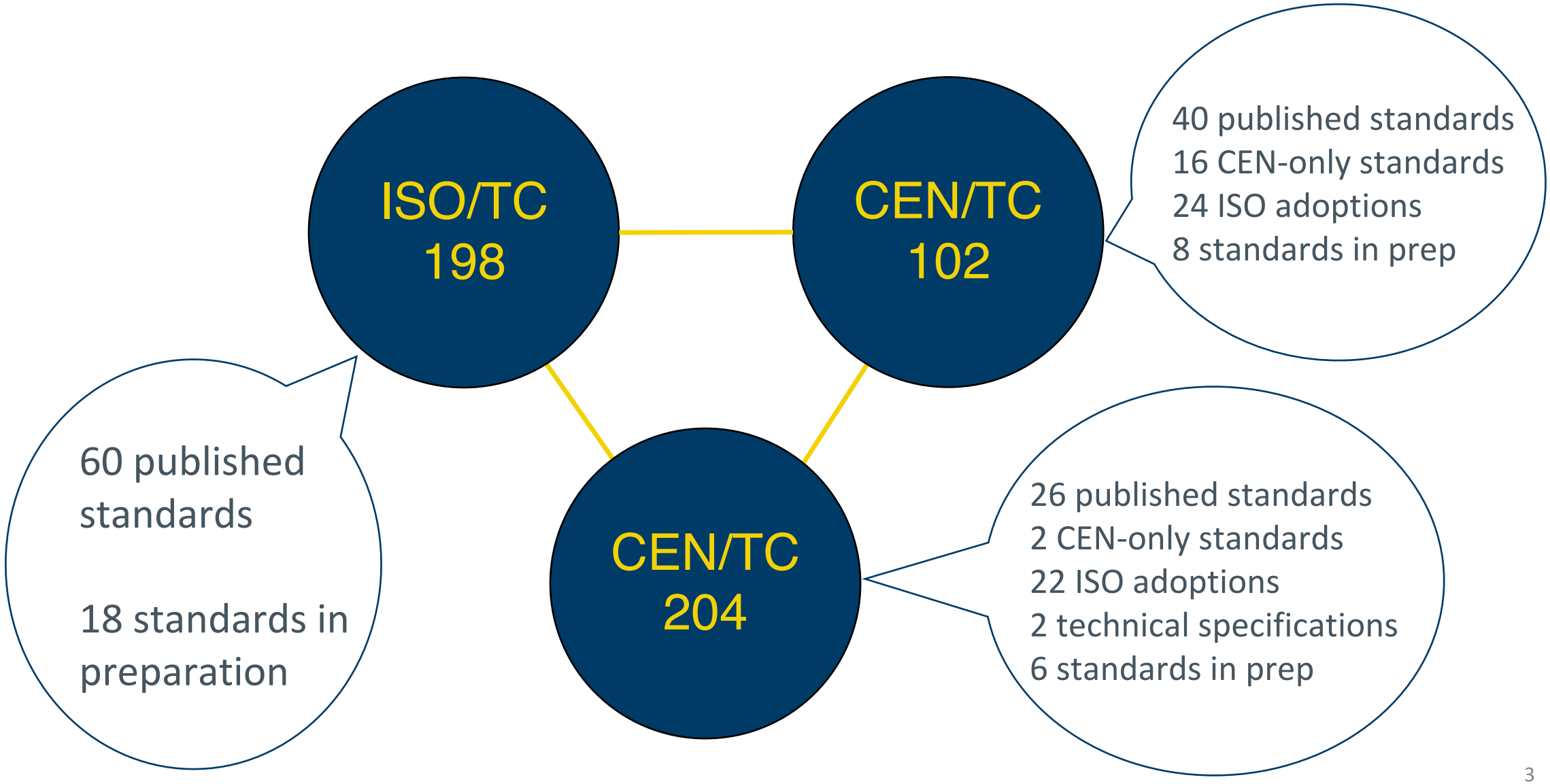
Objectives

CEN and ISO standards have provided a consensus-developed way to assist in compliance to the legal requirements of medical device reprocessing.

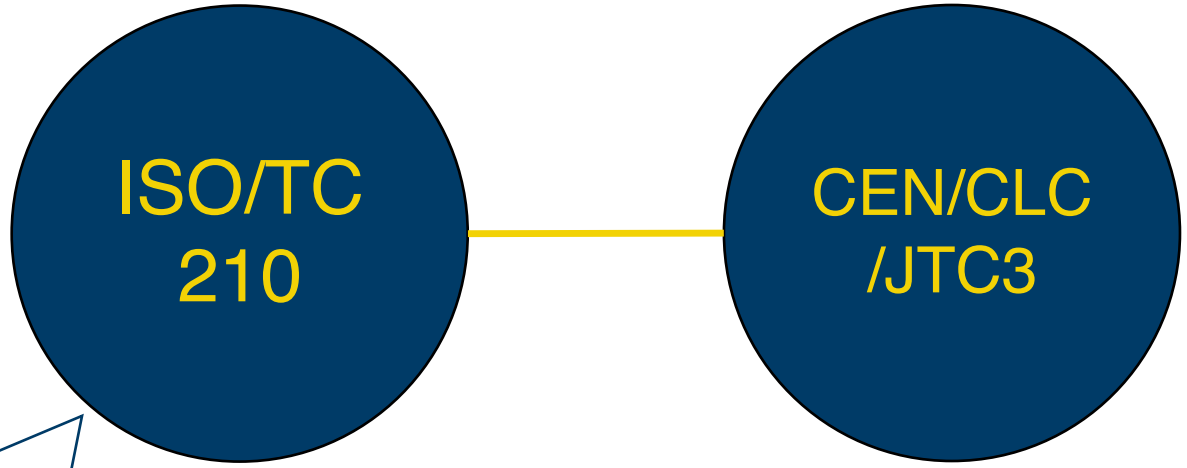
- Medical devices are facing huge regulatory overhaul in Europe as a consequence of the medical device regulation 2017/745 (MDR).
- CEN and ISO standards are continually being drafted, revised and amended to adopt state of the art practices, but are now needing to be additionally modified to reflect the new regulatory requirements of the MDR as well as changes to UK medical device law

This session will outline the key standards that are being developed, revised or amended that relate to the reprocessing of reusable medical devices and some of the processes that dictate the implementation of these new and revised standards.

CEN & ISO Sterilization Technical Committees



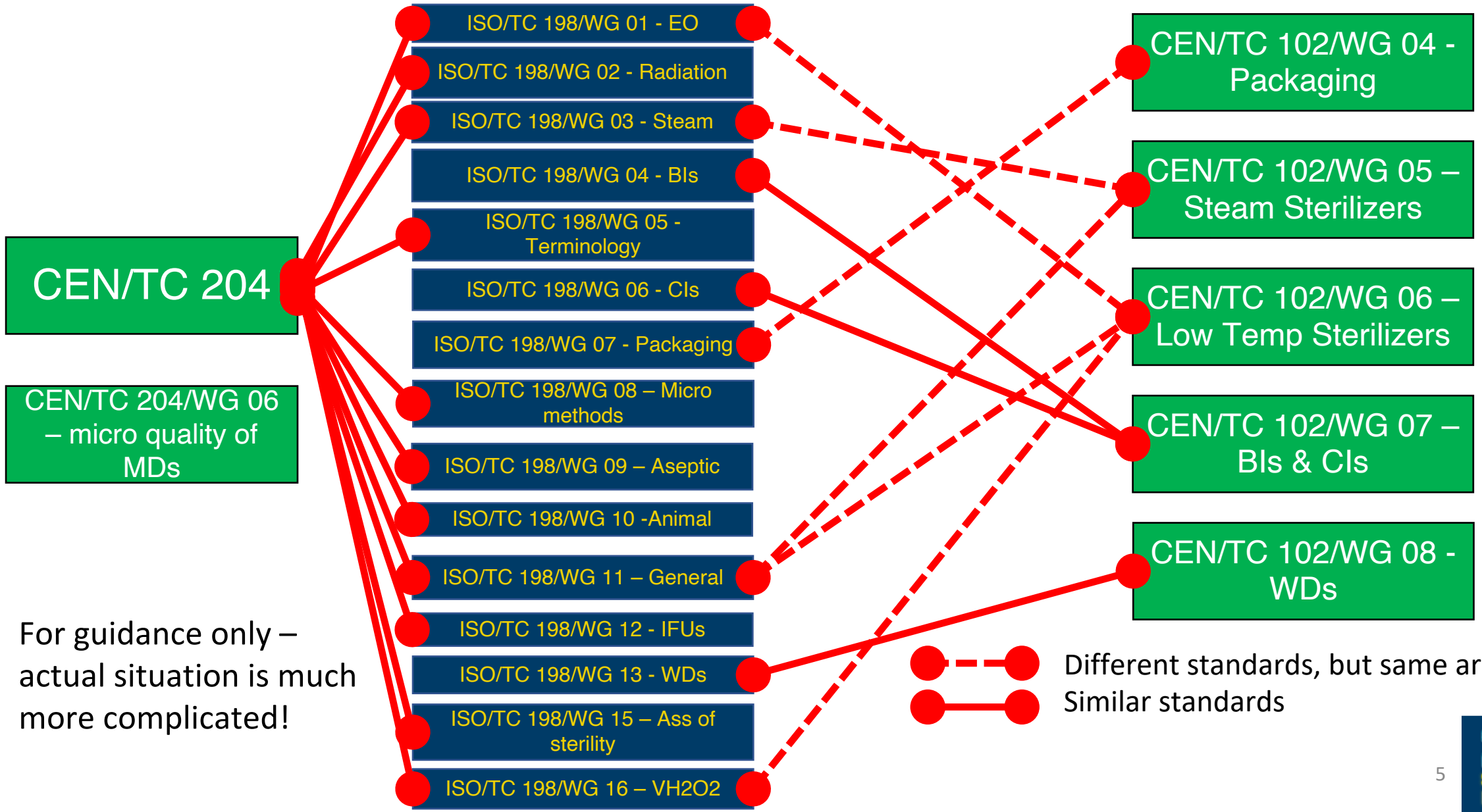
CEN & ISO Quality Management Committees



32 published standards
4 standards in preparation

21 published standards
4 CEN-only standards
17 ISO adoptions
5 standards in preparation

Relationship between CEN/TC 204, ISO/TC 198 & CEN/TC 102



For guidance only – actual situation is much more complicated!

Harmonised standards

Not all European standards are harmonized!

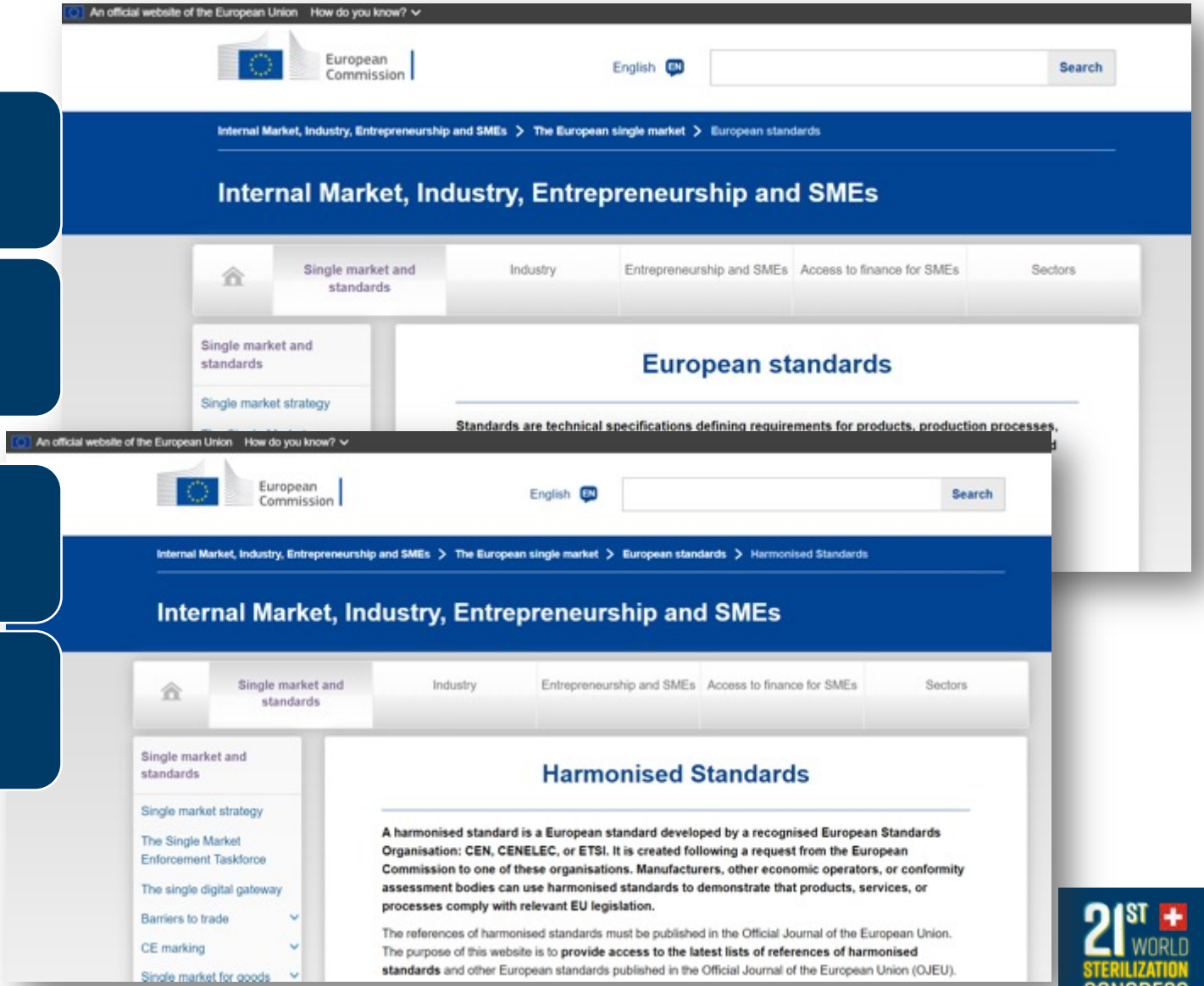
Standards are voluntary

- i.e. conformity is not mandatory

Can provide a *presumption of conformity* to the legal requirements

Products which comply with the relevant Directive or Regulation are allowed free circulation throughout the European Community

- Basis of CE-marking



Development of harmonised standards

Draft standardisation request (SReq) is developed by EC

Draft SReq is voted by EC Committee on Standards

Draft SReq is voted by CEN/CENELEC

Standards are developed or modified with Z annexes that show crosslink of standard's clauses that can be used as a *presumption of conformity* to the legal requirements

Standard is cited in the OJEU

European Commission

CEN CENELEC ETSI

Official Journal of the European Union

English edition Legislation

Current issues

List of standards harmonised with the Medical Devices Directives

- Recent lists published in the OJEU
  - 17/11/2017
  - 20/03/2020
- 264 standards harmonised with the MDD 93/42/EEC
- 46 standards harmonised with the AIMD 90/385/EEC
- 41 standards harmonised with the IVD 98/79/EC

Final amended list published 15/04/2021

- 14 replacements and 4 additions for MDD 93/42/EEC
- 5 replacements and 1 addition for AIMD 90/385/EEC
- 1 replacement and 2 additions for IVD 98/79/EC

List of GB designated standards for UK Medical Devices Regulations 2002/618

- Published 1 January 2021 (0034/21)
- 276 standards designated for SI 2002/618

Standards to be harmonised with the MDR and IVDR

- Standardisation Request M/575

MDR (EU) 2017/745

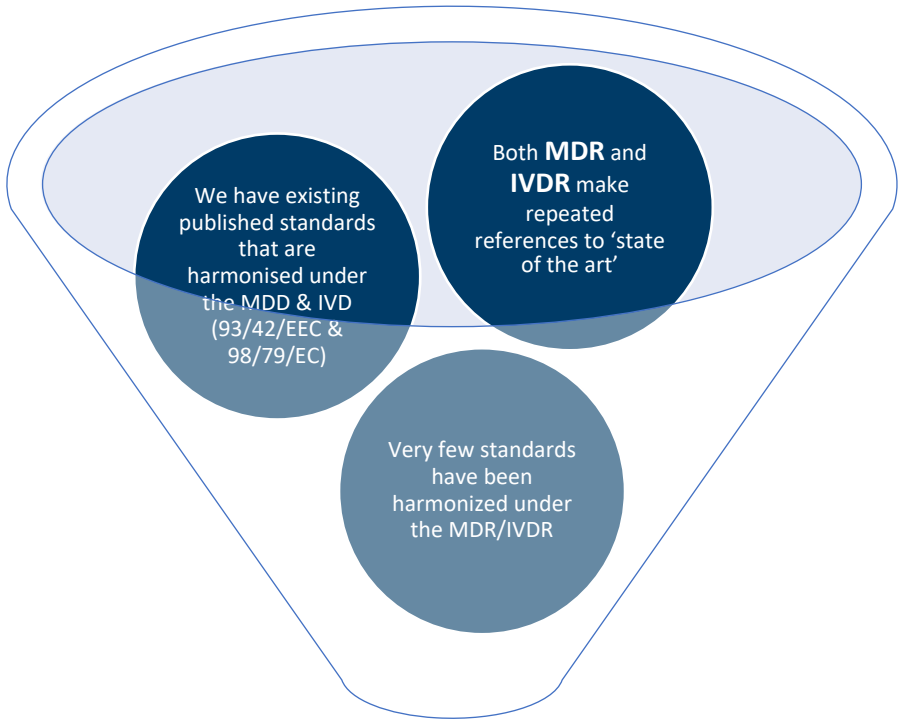
- 201 standards to be amended / revised
- 27 standards to be drafted

IVDR (EU) 2017/746

- 46 standards to be amended / revised
- 3 standards to be drafted

Deadline for standards - 27 May 2024

State of the art - and benefits!



Which standard is state of the art?

Prior edition that was harmonised?
or
New (current) edition that isn't yet harmonized?

General consensus is that the LATEST VERSION is considered state of the art – regardless of harmonised status

Users of standards get a clear interpretation of application of how clauses of a standard allow conformity to ERs/GSPRs

Stakeholders are both industry, healthcare, notified bodies and competent authorities

Harmonised European standards & presumption of conformity

Medical Devices Regulation (MDR) (EU) 2017/745

In Vitro Diagnostic Medical Devices Regulation (IVDR) (EU) 2017/746

- Article 8 (in both regulations):

'Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof'

Understanding latest edition...

In an ideal world, CEN/CENELEC adoptions of ISO/IEC standards have the same date of publication

Addition of annex ZA/ZZs will require revision or amendment of CEN/CENELEC standards with new dates

Additional tier of GB designated standards

For example, these versions could all have the same normative text and differ only in the addition of annexes ZA/ZZ/NZ

- ISO XXXX:2009 adopted as EN ISO XXXX:2009+A1:2021
- ISO XXXX:2009 adopted as EN ISO XXXX:2021
- ISO XXXX:2009 adopted as BS EN ISO XXXX:2022?

So what is topical?

There are 41 standards in development

But here are some highlights

- In no order of importance…

EN ISO 17664-1:2021 and EN ISO 17664-2:2021

EN ISO 17664 - Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

- First published in 2004

Specifies information to be provided by the MD manufacturer on the processing of MDs claimed to be re-sterilizable and MDs intended to be sterilized by the processor

Extensively revised version published in 2017 with:

- Title change
  - Processing of health care products - Information to be provided by the ***medical device*** manufacturer for the processing of medical devices
- Document scope includes disinfected (as opposed to sterile) devices e.g. Endoscopes

New edition published in 2021 to re-designate as part 1, due to publication of part 2

- **Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices**
- **Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices**

ISO 11135 & ISO 11137

ISO 11135-1 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

- Revision is currently underway

ISO 11137-1 Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices

- Revision is currently underway
- A series of task groups are working on different sections of the standard

Biological indicators - ISO 11138

Sterilization of health care products — Biological indicators – part 8. Validation of a reduced incubation time

Specifies requirements for validating an incubation time that is less than the ‘standard’ 7 days

Initial work was based on a new method that was ultimately abandoned, but current standard is based on existing US FDA method for a reduced incubation time

- Published July 2021

Sterilization of health care products — Biological indicators – part 6.Biological indicators for vaporized hydrogen peroxide sterilization processes

Specifies requirements that are applicable to biological indicators for VH2O2 sterilization processes

Work has been slow due to variability found in inter-laboratory testing

Inter-laboratory tests are continuing

- Publication not expected before 2023/2024

Chemical indicators - ISO 11140

ISO 11140-1 was published in 2014

Document confirmed in January 2021 as part of ISO's 5-year systematic review

- Early revision may occur if sufficient progress is made with the other parts of the series requiring revision

Requirements aligned with test equipment that is specified in ISO 18472

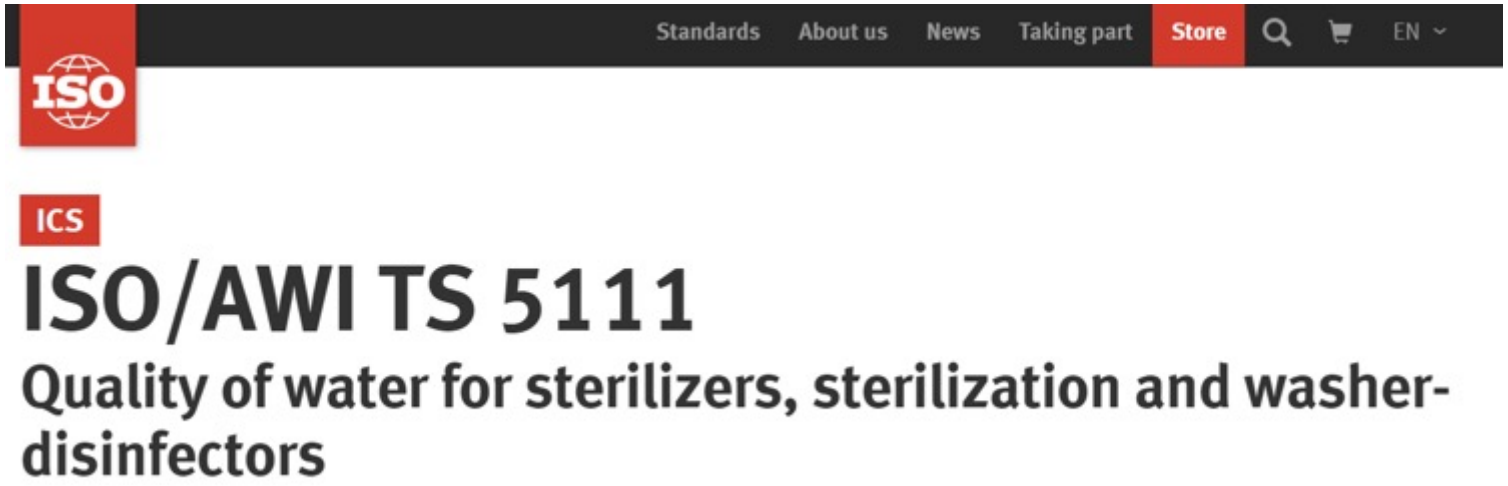
ISO 11140-6 is draft for 'hollow' and 'porous' devices for testing small steam sterilizers

Work started a long time ago (more than 10 years) to replace EN 867-5:2001

Committee issues largely resolved; draft document progressed to Draft International Standard (DIS) in 2021 with positive result

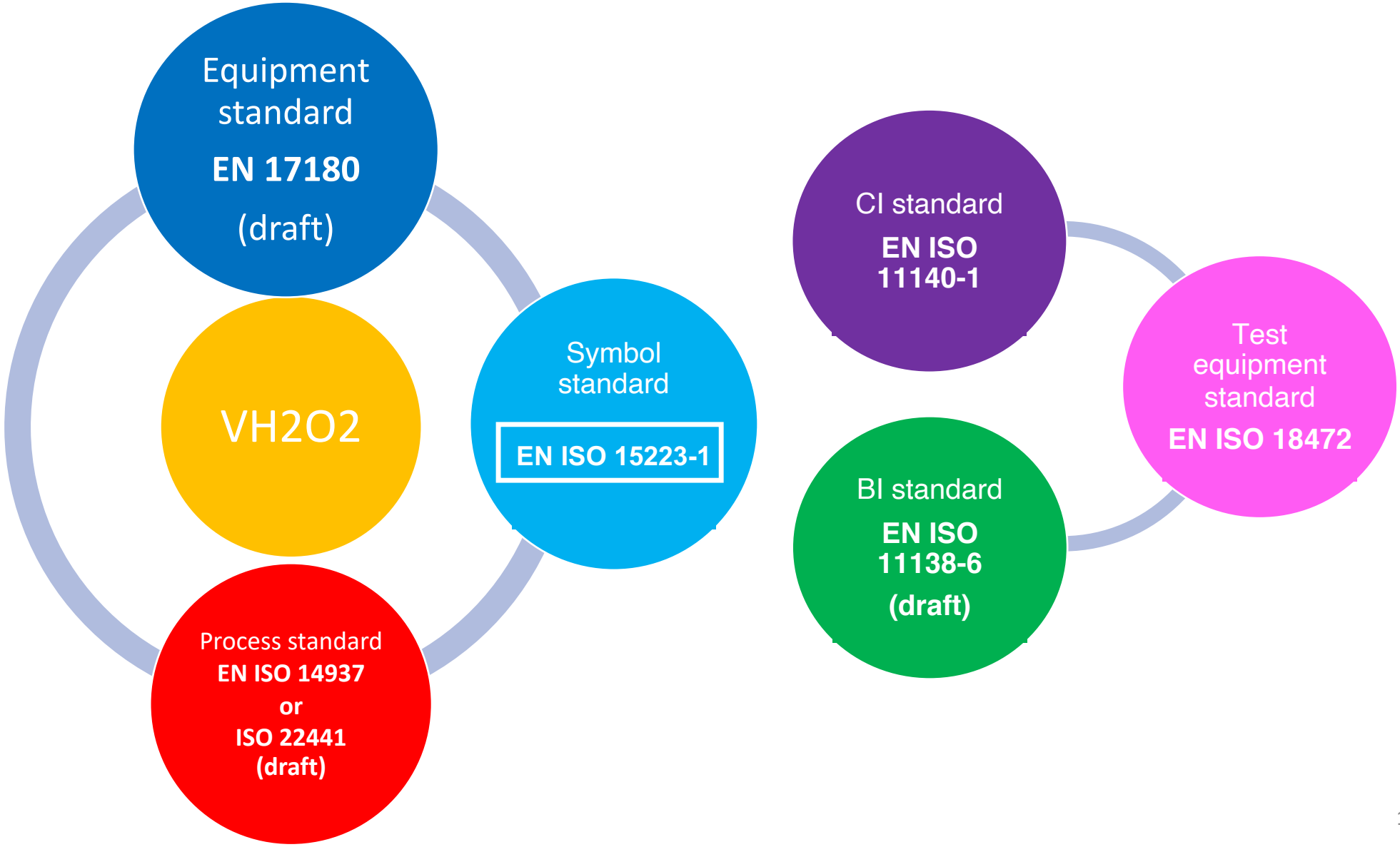
Comments to be resolved by end of 2021 and publication expected in first half of 2022

ISO/TS 5111



- Approved ISO work item to generate a technical specification for water quality
- Intention is not to redefine water quality from source sterilizer and sterilization standards
- Use a standard format and presentation of requirements
- Use common terminology

Standards for VH2O2 sterilization



Sterilizers for VH2O2 - EN 17180 (draft)

- Work started in 2015
- prEN 17180 was formally balloted in 2017
- Result was negative…

Work began in 2015/2016

Work was restarted in 2019

- Restarted as PWI (preliminary work item) due to exceeding the CEN time limit for development

- 2-3 year development
- Publication in 2024?

Will become formal work item in 2021

Issues include scope and definition of 'residual' H_2O_2

- Residues in medical devices (ISO 10993)
- Residues during operation (IEC 61010)
- Residues when door is opened

- Termed 'penetration type test device' (PTTD)

'Process challenge' for defining minimum sterilizing agent penetration

Result of voting

(National Members having abstained are not counted in this vote.)

Disapproved by National Members

National Members approving: 15
National Members disapproving: 7
Number of Members approving: 68.182 % (requirement >= 55 %)
Weighted percentage of Population approving: 54.253 % (requirement >= 65 %)
EEA Members approving: 12
EEA Members disapproving: 7
Number of EEA Members approving: 63.158 % (requirement >= 55 %)
Weighted percentage of EEA Population approving: 45.016 % (requirement >= 65 %)

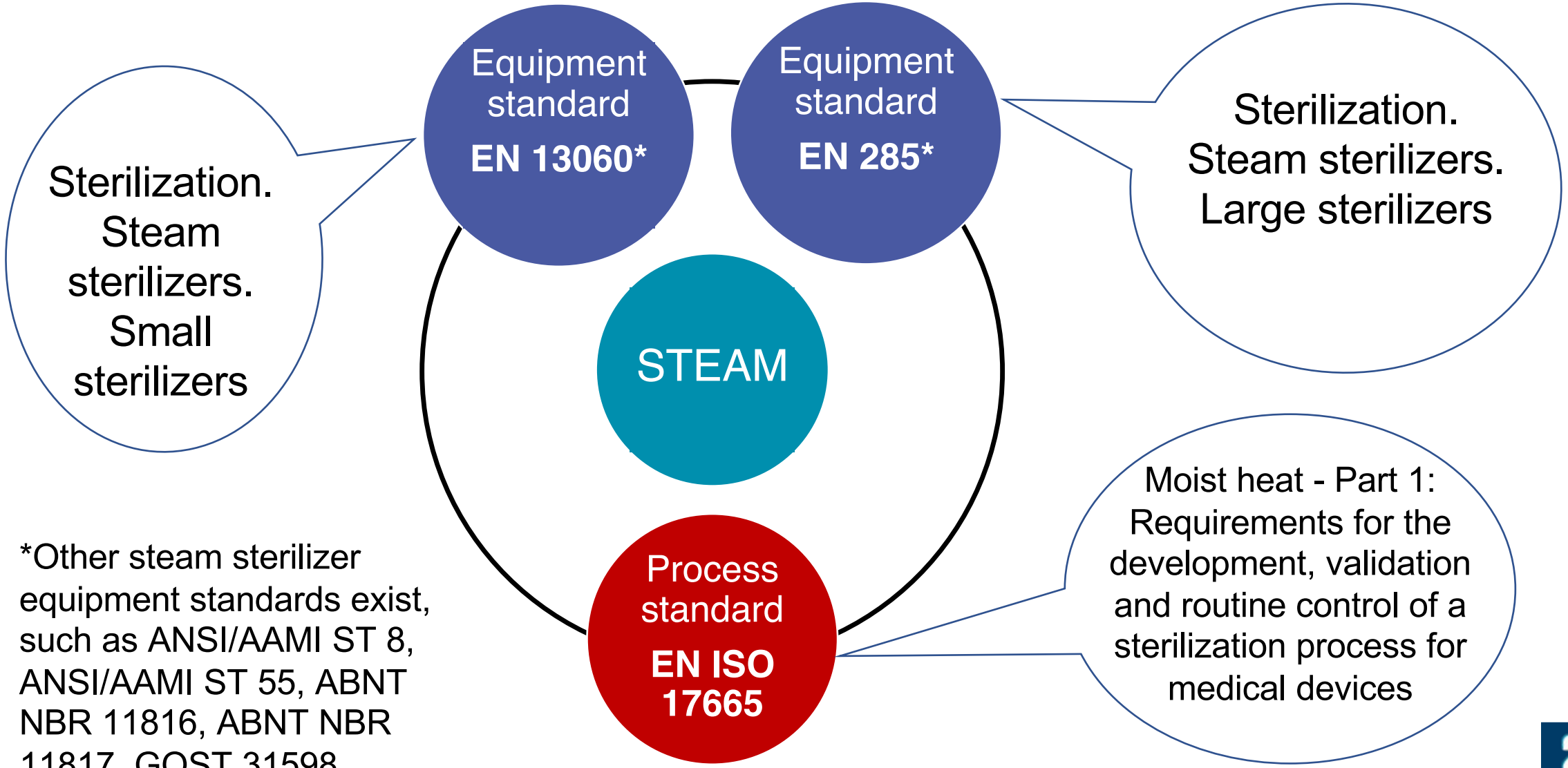
VH2O2 process standard - ISO 22441(draft)

ISO approved work to develop a new *process* standard in 2017 specifically for low temperature vaporised hydrogen peroxide sterilization

Structure based on EN ISO 14937, but with specific application for VH2O2

DIS ballot closed in early October 2021. Publication expected by May 2022

Standards for steam sterilization



*Other steam sterilizer equipment standards exist, such as ANSI/AAMI ST 8, ANSI/AAMI ST 55, ABNT NBR 11816, ABNT NBR 11817, GOST 31598

ISO/TS 22421

Common format for sterilizer standards

ISO/TC 198 do not have specific requirements for sterilizers

- These are given in national or regional standards, but similar requirements are expressed differently in these standards

ISO/TS 22421 is a technical specification that aligns many disparate sterilizer requirements; published January 2021

Cover such aspects as:

- Material, design and construction
- Chamber requirements
- Doors and interlocks
- Noise, heat, vapour, vibration and EMC emissions
- Quality & risk management
- Safety requirements
- Service and local environment
- Information to be provided by the manufacturer
- Test equipment etc


PD ISO/TS 22421:2021

TECHNICAL SPECIFICATION

ISO/TS 22421

First edition
2021-01

Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

Stérilisation des produits de santé — Exigences communes applicables aux stérilisateurs utilisés pour la stérilisation terminale des dispositifs médicaux dans les établissements de santé

ISO

Reference number
ISO/TS 22421:2021(E)

© ISO 2021

Standards to be initially aligned with ISO/TS 22421 format:

- EN 1422 (EO sterilizers)
- EN 17180 *draft* (VH2O2 sterilizers)
- EN 14180 (LTSF sterilizers)
- EN 13060 (small steam sterilizers)
- EN 285 (large steam sterilizers)

Steam process standard - ISO 17665

ISO published standard in 2006, guidance (part 2) in 2009 and product families in 2013

ISO 17665 is being revised as a single standard that incorporates parts 1, 2 and 3

Much discussion on:

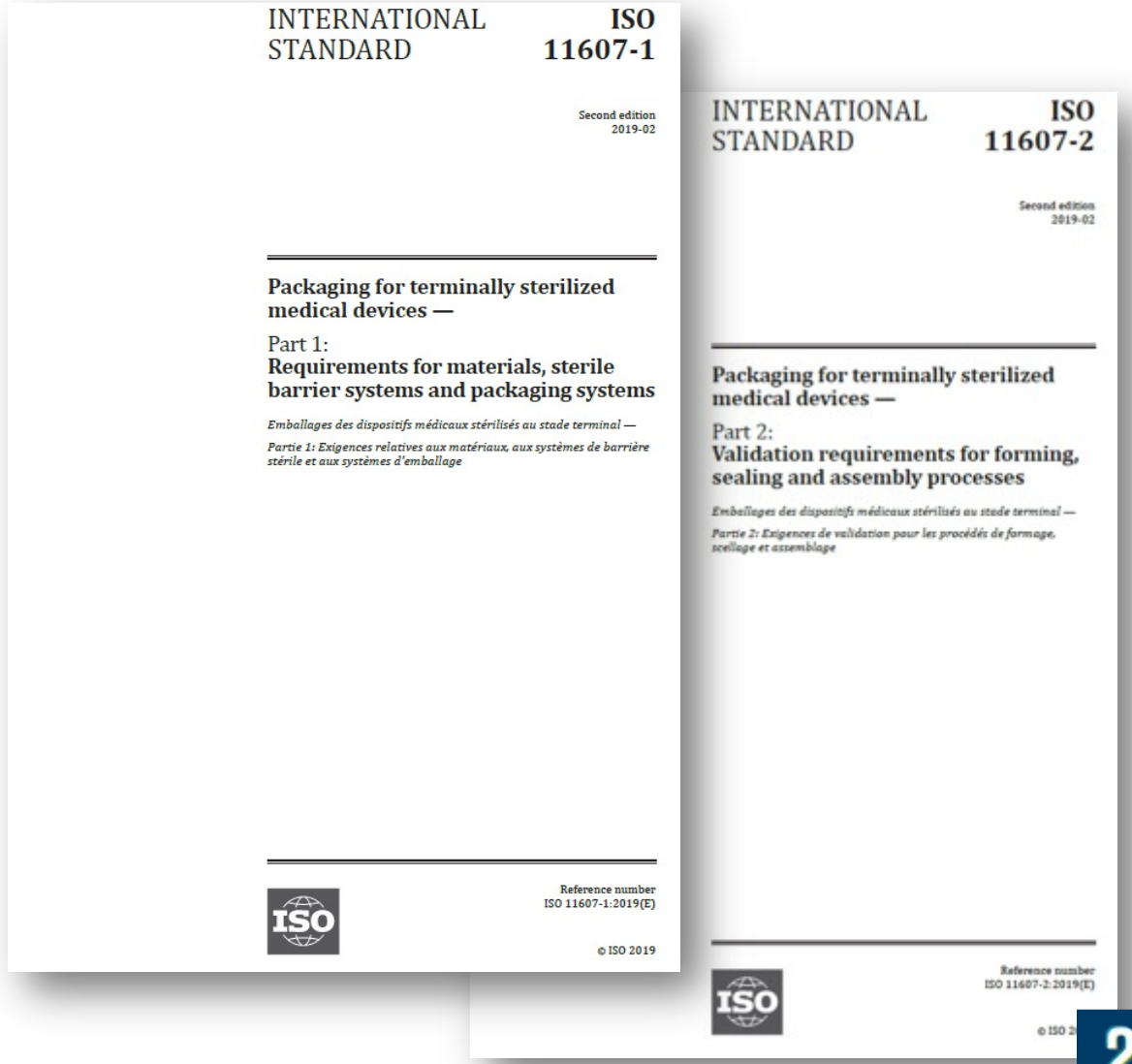
- Description of ‘steam’
- Independent monitoring

Published before 2022/2023

ISO 11607-1 and ISO 11607-2

Both parts revised and published in 2019

Amendments underway for both parts



Washer-disinfectors – ISO 15883 series

Part 1: General requirements, terms and definitions and tests

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

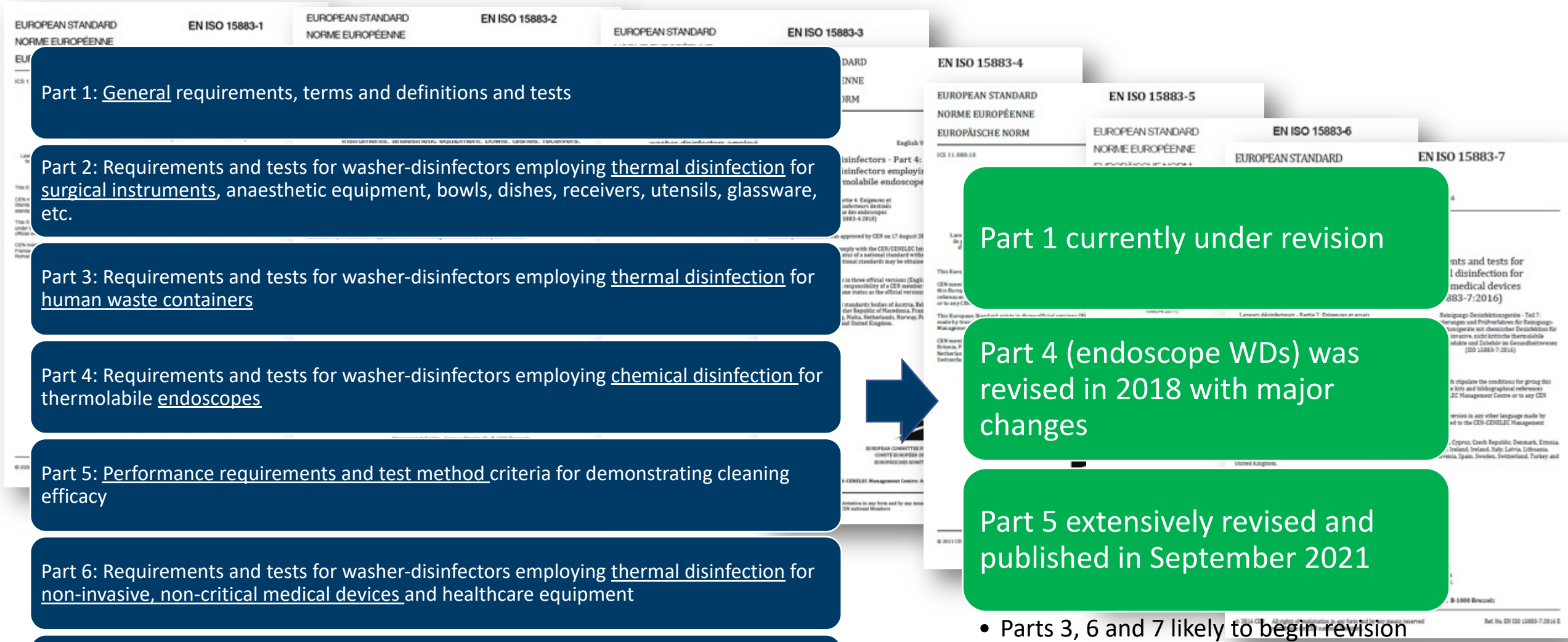
Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment



Part 1 currently under revision

Part 4 (endoscope WDs) was revised in 2018 with major changes

Part 5 extensively revised and published in September 2021

- Parts 3, 6 and 7 likely to begin revision shortly

Washer-disinfectors – ISO 15883-5:2021

Requires that cleaning efficacy be determined by visual examination and by the quantitative detection of protein (4.4.1)

For invasive medical devices, at least one other validated quantitative analytical test method shall be used to measure another analyte(s) in addition to protein for type testing

All proteinaceous test soils must be validated to meet requirements for minimum performance given in ISO 15883-5:2021

ISO 15883-5:2021 Requirements		
Test condition	Time	Residual soil remaining
Water, 25 °C	30 secs	≥12% protein remaining
Water, 25 °C	90 secs	≥2% protein remaining
Water, 75 °C	30 secs	≥12% protein remaining
Water, 75 °C	90 secs	≥6% protein remaining

Washer-disinfectors – ISO 15883-5:2021

ISO 15883-5:2021 specifies a protein level lower than 6.4 micrograms per square centimetre (6.4 µg/cm^2) and is independent of instrument size

As the size of reusable surgical instruments varies, there is a discrepancy between the EN ISO 15883-5:2021 requirements and those specified per instrument (e.g. Germany, Austria) or per instrument side (e.g. UK)

In consequence, practitioners will have conflicting requirements between some national guidance and of EN ISO 15883-5:2021 for residual protein levels, depending upon the size of the reusable surgical instrument:

- Smaller surgical instruments will be able to significantly exceed the ISO 15883-5 protein requirements, yet still meet some national guidance requirements
  - Surgical instruments used for high-risk procedures such as neurosurgery are typically smaller in size
- Conversely, larger surgical instruments will be able to significantly exceed some guidance requirements for residual protein, yet still meet the ISO 15883-5 protein requirements.

Action levels:

• **Protein**	**6.4 µg/cm^2**
• TOC (total organic carbon)	12 µg/cm^2
• Carbohydrate	1.8 µg/cm^2
• Haemoglobin	2.2 µg/cm^2
• Endotoxin	20 EU/device
• ATP	22 femtomoles/cm^2

Alert levels :

• **Protein**	**3 µg/cm^2**
• TOC (total organic carbon)	6 µg/cm^2
• Carbohydrate	0.9 µg/cm^2
• Haemoglobin	1 µg/cm^2
• Endotoxin	2.2 EU/cm^2
• ATP	10 femtomoles/cm^2

Symbols for medical devices - ISO 15223-1:2021

The MDR and IVDR require manufacturers to provide specific labelling on medical devices

- This can be a problem in Europe with the need to translate this information into 24 EU languages

ISO 15223-1 has been revised with 20 new (additional) symbols

- Symbols can be used to replace text on medical device labelling

Includes new symbols that meets the Regulations' requirement to indicate 'medical device' & 'method of sterilization'

New symbols for medical device and VH2O2