

ISO TC84 Scope and Sharps Protection

***A presentation for
European Biosafety Network
Webinar***

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ISO-TC84 Chair, 2022-2024

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Objectives of this talk:

1. Scope of ISO TC84 standards
2. Role of Sharps Protection

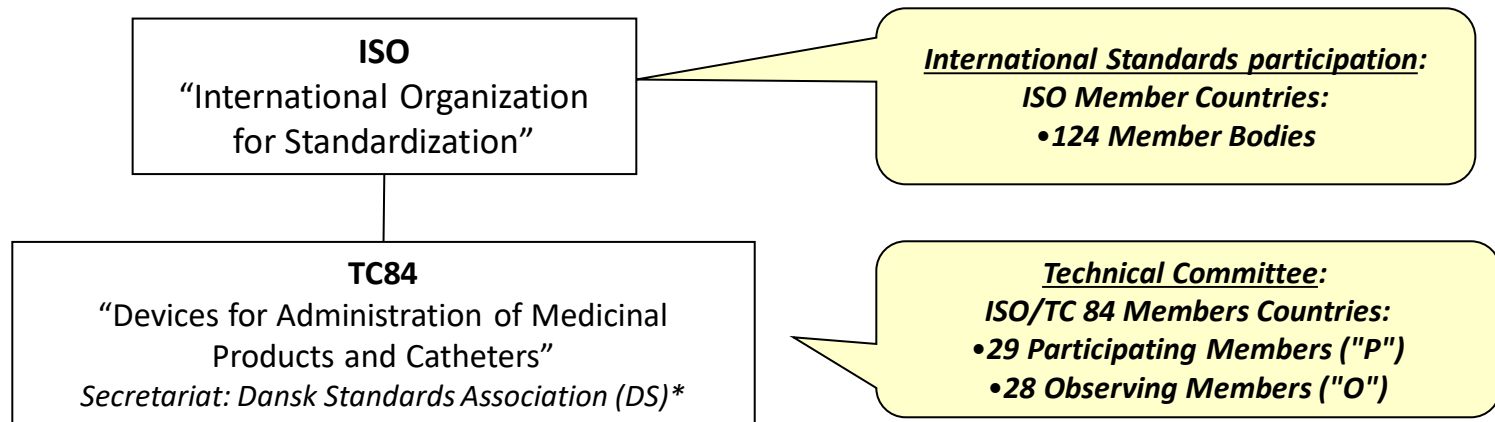


Technical Committee TC84

“Devices for administration of medicinal products and catheters”

Scope of ISO TC84:

- *“Devices for Administration of Medicinal Products and Catheters”*
- Covers medical devices for therapeutic drug delivery.



**Danish Standards (DS) is the ISO Secretariat for TC84 and its working groups (WGs).*



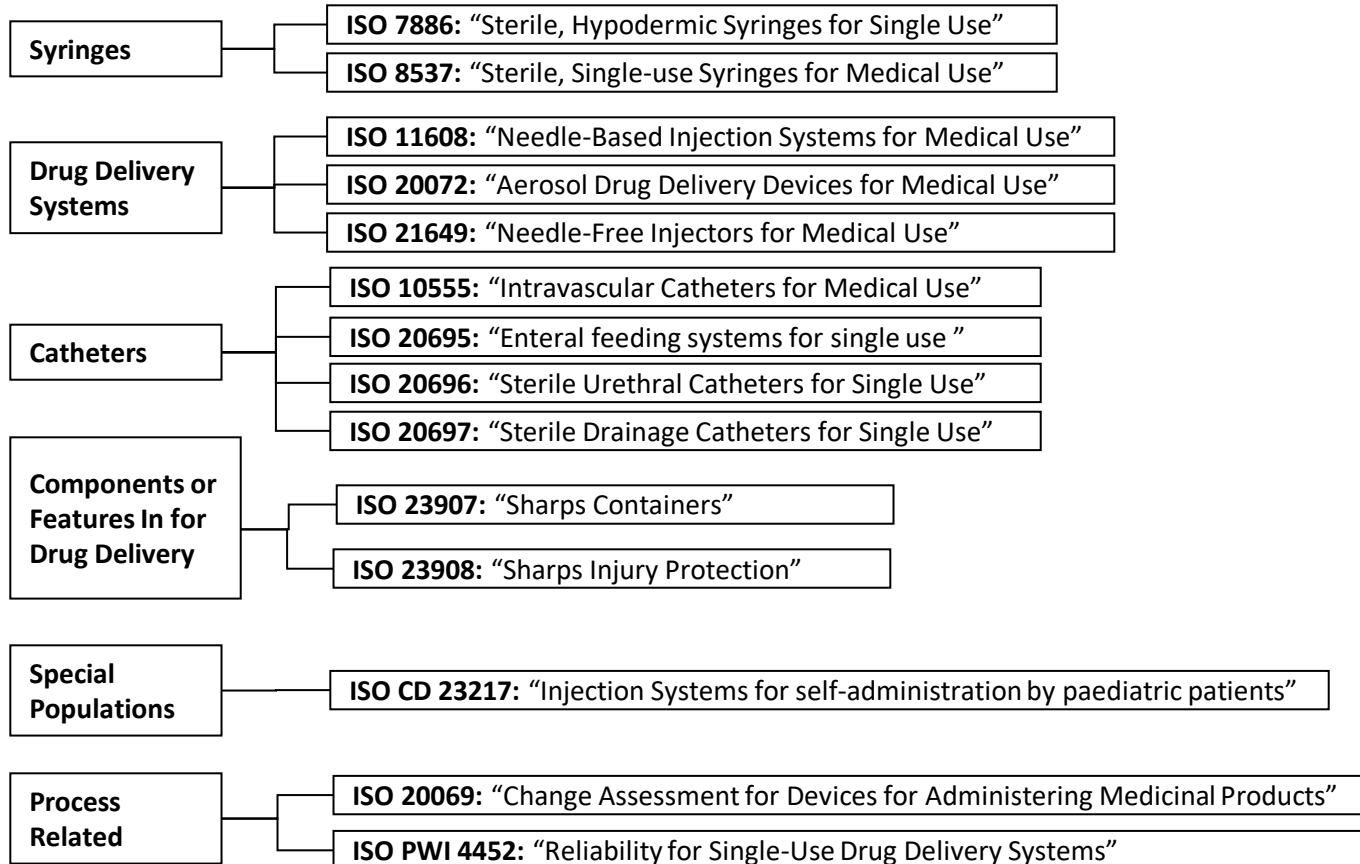
What kinds of devices are covered by TC84?

- Needle-based Injection Systems, including:
 - Pen-injectors
 - Auto-Injectors
 - On-Body Delivery Systems
- Syringes
- Needle-free Injectors
- Aerosol Drug Delivery devices
- Catheters
- And other devices



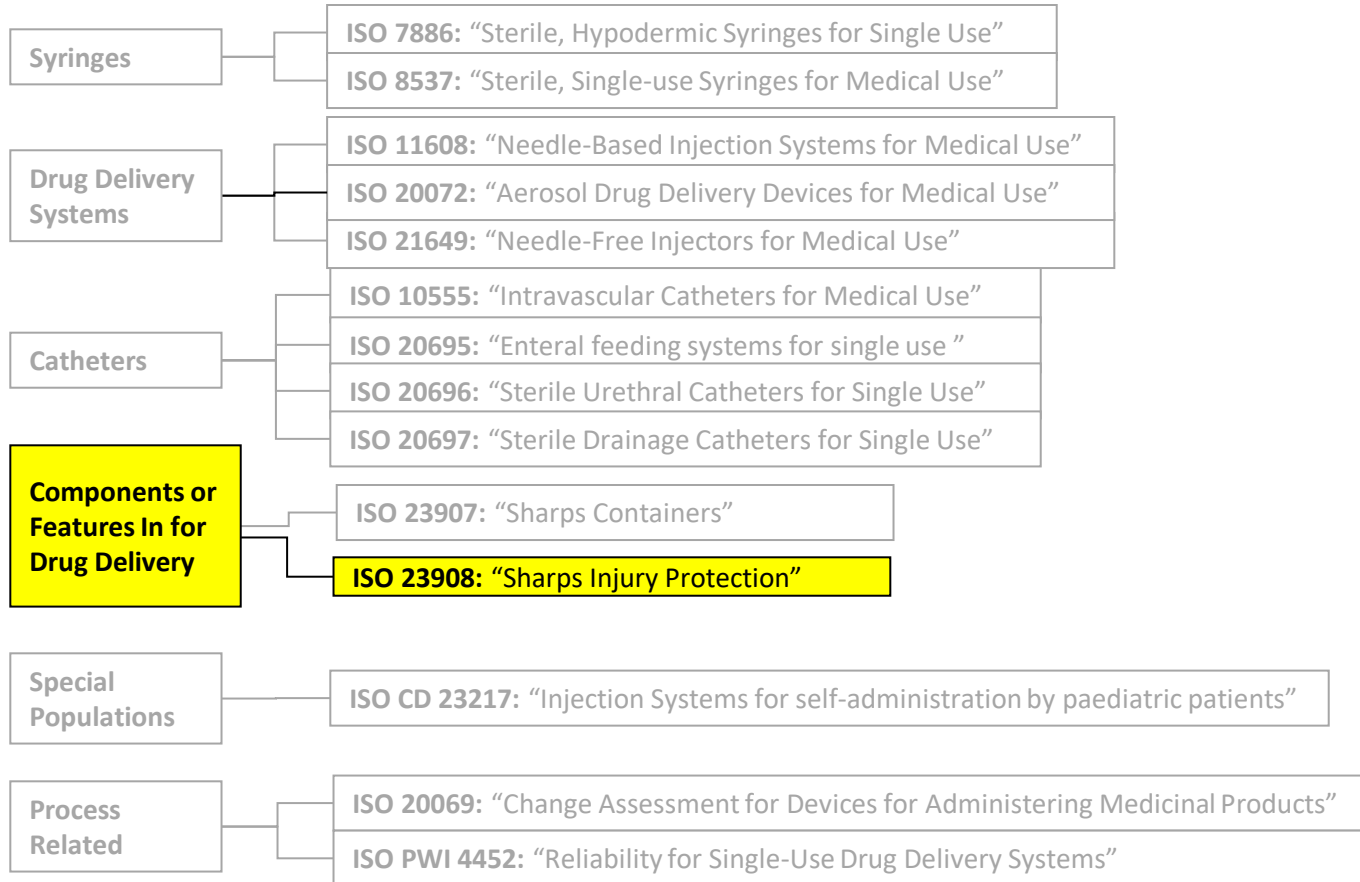
What kinds of devices are covered by TC84?

ISO TC84: “Devices for Administration of Medicinal Products and Catheters”



... and if you claim **Post-Use Sharps Protection**:

ISO TC84: “Devices for Administration of Medicinal Products and Catheters”



Many ISO/IEC Standards impact Delivery Systems:

Standards which address Syringes:

ISO 9626: Stainless Steel tubing
ISO 7886-1: Single use syringes
ISO 7886-2: Syringes for syr. pumps
ISO 11040-5,-6,-8: Pre-filled syringes

Other Standards which may apply:

IEC 60601-1: Medical Elect. Equip.
IEC 60601-1-8: Alarms
IEC 60601-1-11: Home Healthcare
EN 62304; IEC 80002-1: Software
IEC 15026-1,-2,-4: Systems & Software Engineering
IEC 60601-2 IEC 61000-4; and
CISPR 11 -14-1: EMC
IEC 60812: Dependability

Pump-specific Standards:

IEC 60601-2-24: pumps
 ...if the NIS is a rate-based pump

Other Standards which may apply:

EN 1615, 1618: catheters, tubing
ISO 80369-1: connectors
ISO 11070: IV introducers + guide wires
 ...if it requires connectors/catheters

If the device is a Needle-based Injection System (NIS):

ISO 11608 family of standard: addresses:

Part 1 The “parent” document for parts 2-7, it addresses key requirements for a NIS

The NIS may also have to address the following:

Part 2 ... if, mated with a needle, it becomes a “system”.

Part 3 ... if the NIS contains a finished medicinal product container or fluid path (OBDS)

Part 4 ... if it contains electro-mechanical components, electronics, firmware, software and/or batteries.

Part 5 ...if the NIS has an automated function (e.g., needle insertion) or the device limits access to a function.

Part 6 ... if the NIS is an On-Body Delivery System (OBDS)

Part 7 ...If it is claimed for persons with visual impairment

+

ISO 23908: ...if the NIS claims post-use sharps protection.

+

ISO CD-23217: ...if it is aimed for pediatric self-administration.

+

ISO CD-4452: ... RE: reliability of single-use Devices

If it delivers medication without a needle:

ISO 20072: Aerosol Drug Delivery Devices

ISO 21649: Needle-free Injection Systems.

... whether it has a needle or not, it may also need:

Process Standards:

ISO 14971: Risk Management

IEC 62366: Usability Engineering

ISO 10993-3; -10 and -11: Biological compatibility

ISO 20069: Guidance for Change Assessment and Evaluation to Drug Delivery Systems

ISO 11135: Sterilization

ISO 15223: Symbols

ISO 4452: Reliability for Single-Use Drug Delivery Systems

pending: Sustainability

KEY: ISO= International Organization for Standardization

IEC = International Electrotechnical Commission

EN = European Norm



... of those, which are TC84 standards:

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KEY: TC 84 Standards



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Thank You



Questions?

