ISO/TC 84/WG 8
and
EN ISO 23908 revision

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ISO/TC 84 WG8 “SHARPS CONTAINERS”

- Under ISO/TC 84, WG8 is responsible for:
  - **EN ISO 23907-1** (single use sharps container)
    - **ISO 23907-2** (reusable sharps container)
      - **EN ISO 23908** (sharps protection mechanisms)

- WG8 has experience in testing methods for preventing the risk of unintended cuts and pricks, body fluid exposures and microbial contamination

ISO Working groups

Participation:

- Participants are appointed by national standardization bodies (NSB)
- Liaison can be requested by other technical committee or organization
- The WG convenor may invite a single guest to a single meeting provided that s/he informs ISO/NSB before the meeting.

WG 8 MEMBERS LIST

Convenor: M. Thomassin François

Members:

ANSI (FDA, BD, AbbVie), **BIS** (Aimindia) **BSI** (Frontier Group, Danielsheaths, Sharpsmart, Daniels), **DIN** (BGW, Sarstedt, BBraun, Sanofi, Boehringer-Ingelheim), **DS** (Novonordisk), **JISC** (Terumo, Tokyo Institute of Technology), **KATS** (Dr Kyung Sool, Mr Yong Wan, Mr Jungk Won, Pr Young Kon, Mr Jae-Hyun, National Institute of Medical Device Safety Information), **AFNOR** (Keter, Dastri, Geres, Hospidex, Isoperma, LNE, BD), **SCC** (Dr Grimmond, Daniels Healthcare), **SA** (staffandpatientsafety) **SNV** (Confinis, Ypsomed), **SIS** (Regulatory authority) **UNE** (Mr Martinez Lazaro, Amedics, Spanish Nursing Council, BD), **UNI** (Ditta 2001,Artsana)

Liaison representative: **European Biosafety Network, UNICEF, WHO**

➔ **14 countries / 63 experts**

ISO/TC 84 WG8

WG8 Meetings (all Virtual):

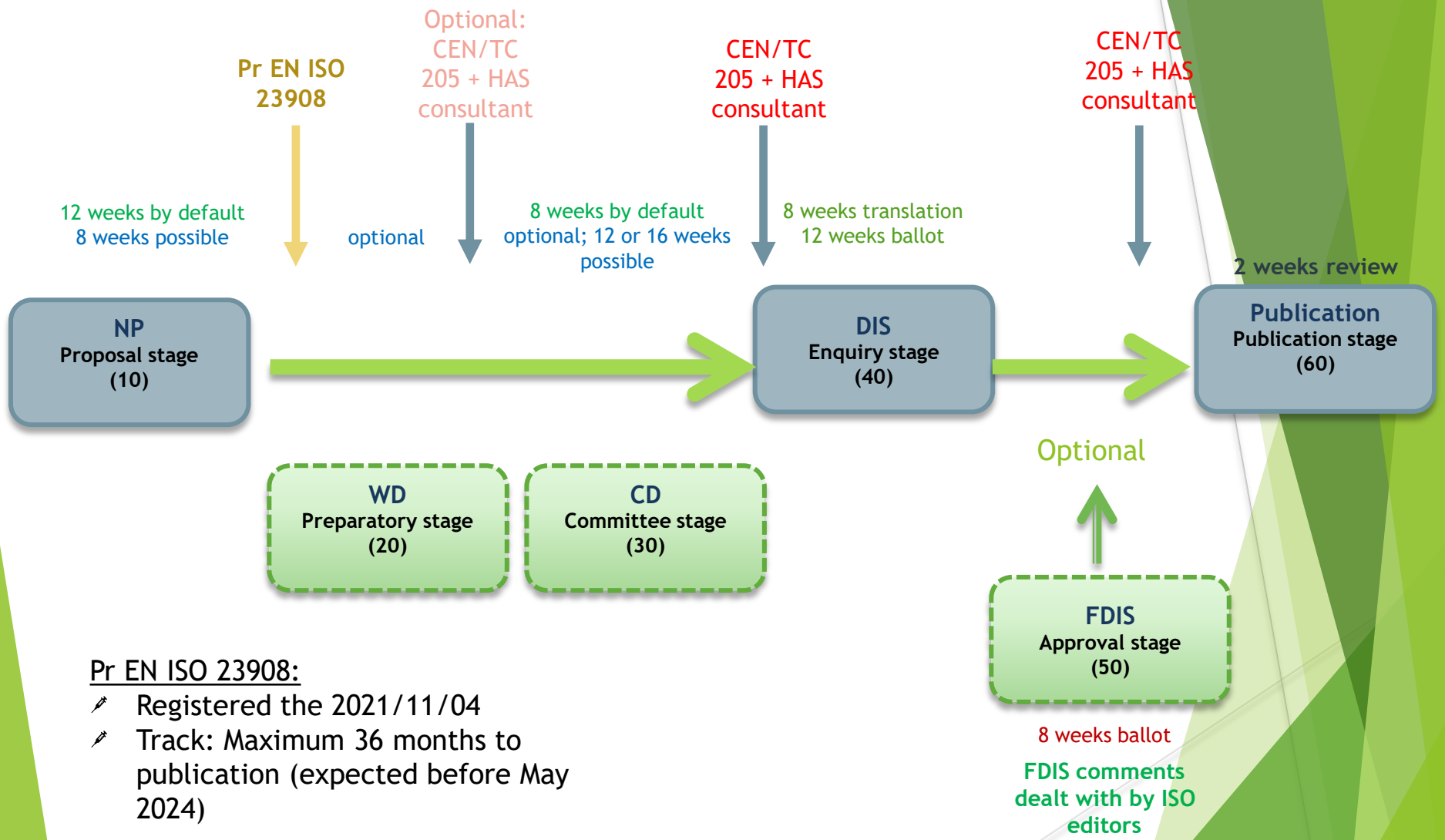
- Kick off: 16-12-2021
- 28-02-2022
- 03-05-2022
- 25-05-2022
- **06-07-2022**

Sub-Groups:

- New tests: 20/01, 31/03, 27/04, 12/05, 21/06, 28/06
- Terms and definitions: 19/01
- Simulated user study: 20/01
- Annex ZA: 10/06

And now, to focus on pr EN ISO 23908 revision

ISO STANDARD DRAFTING PROCESS: PR EN ISO 23908



Pr EN ISO 23908:

- Registered the 2021/11/04
- Track: Maximum 36 months to publication (expected before May 2024)

PR EN ISO 23908REV AND M/575 - TITLE

EN ISO 23908:2011

Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Pr EN ISO 23908

Sharps injury protection -- Requirements and test methods -- Sharps protection mechanisms for single-use needles, introducers for catheters **and needles used for blood testing, monitoring, sampling and medical substance administration**

M/575

Brussels, 14.4.2021
C(2021) 2406 final

COMMISSION IMPLEMENTING DECISION

of 14.4.2021

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

➔ **Enlargement according to the standardization request**

PR EN ISO 23908REV – NEW SCOPE

INTERNATIONAL· STANDARD¤

Pr·ISO 23908

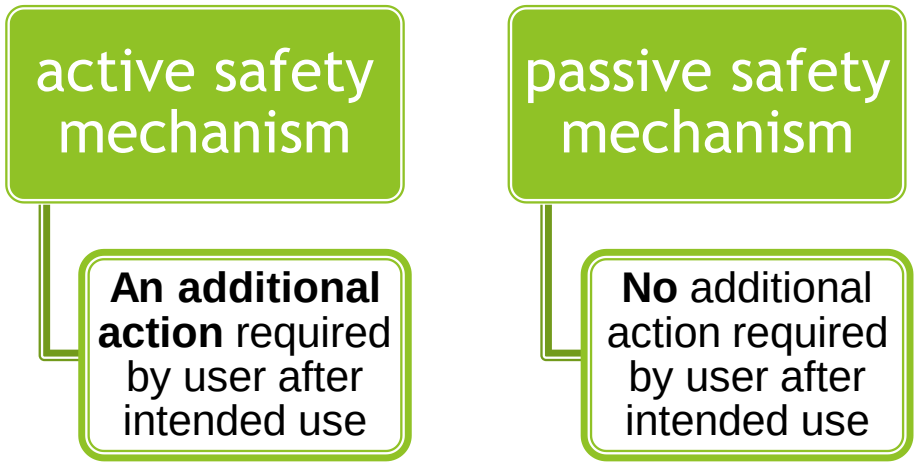
Requirements and test methods for testing the performance and usability of sharps injury protection mechanisms forming part of devices fitted with single use 'sharps', for **administration and/or extraction of body/blood fluids and/or medicinal substances**.

The aim of the tests are to confirm **minimization of risks of accidental sharps injury from contaminated 'sharps', after the period of intended use, *including the path to final disposal*.**

It does not give requirements for the storage and handling of the device, sharps, or sharps protection before the sharp is used to penetrate the tissue.

Sharps·injury·protection·---·Requirements· and·test·methods·---·Sharps·protection· mechanisms·for·single-use·needles,· introducers·for·catheters·and·needles· used·for·blood·testing,·monitoring,· sampling·and·medical·substance· administration¤

PR EN ISO 23908REV - TERM AND DEFINITIONS



- Integrated/built-in and stand-alone safety mechanism
- The term ‘Devices’ (as opposed to ‘Medical Devices’ covers product for administration and/or extraction of body/blood fluids **and/or** medicinal substances (example: pre-filled syringes)
- Accidental sharp injury, contaminated sharps and final disposal (until recycling or final destruction)

PR EN ISO 23908REV

Slides hereafter, may not reflect the final version to be published and proposed for citation in the OJEU. Revision by the working groups of ISO/TC 84 WG8 is still in progress under and major steps such as DIS/CEN enquiry and HAS assesment are still to come..

Standard body:

- Risk assesment (analysis, evaluation control, evaluation of residual risk) with ISO 14971:2019. EN ISO 14971 has been recently accepted as an MDR harmonized standard.
- Usabilitity enginering in accordance with IEC 62366-1
- In ‘safe mode’, protection against accidental sharps injury under expected conditions of use.
- Test for setting activation force
- Test to challenge the device once in ‘safe’ mode (Drop test, resistance to un-latching, ‘tread test’) – In progress
- Annex A - Guidance on simulated user studies– In progress
- Annex B - test to assess the access to the sharps– In progress
- 1st draft for Annex ZA ready

POSSIBLE MILESTONES AND PERSPECTIVES*

WG8 meeting 06/07/2022	• Finalisation of a first consensual revised draft
Summer 2022	• WD or CD + 1st Assesment from HAS consultant,
September /October 2022	• Resolution of WD/CD comments
2023	• Draft International stage
Early Autonm 2023	• Resolution of DIS comments + finalisation of draft for FDIS
End of 2023/earl y 2024	• FDIS+Publication

*Milestones can change according WG8 and TC 84 decisions