

## L@b Brief Standards Newsletter – September 2023

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### NEW WORK ITEMS PROPOSED

ISO/PWI 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric infusion controllers.

ISO 35001 — Biorisk management for laboratories and other related organisations — Implementation guidance.

prEN 15154-1:2023 Emergency safety showers — Part 1: Plumbed-in body showers for laboratories.

prEN 15154-2:2023 Emergency safety showers — Part 2: Plumbed-in eye wash units.

ISO/PWI 19676 Single particle light interaction methods — Bio-fluorescence airborne particle counter for clean spaces.

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### NEW WORK ITEMS ACCEPTED

Amendment of EN ISO 20857 Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices.

Revision of ISO/TS 22367, Medical laboratories — Application of risk management to medical laboratories.

SO/NP 11607-3, Packaging for terminally sterilised medical devices — Part 3: Requirements for process development for forming, sealing and assembly.

EN 12469-5 Biotechnology Performance criteria for microbiological safety cabinets.

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### DRAFT STANDARDS

#### LAB GENERAL

**ISO/DIS 13318-1 Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 1: General principles and guidelines** has been approved with comments and will go to FDIS.

**ISO/CD 22412 Particle size analysis — Dynamic light scattering (DLS)** a committee draft has been circulated.

**IEC 61010-1/AMD2 ED3: Amendment 2 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements** has been circulated for voting by 6 October.

**IEC 61010-2-011 ED3: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment** has been circulated as a committee draft.

## **IVDs etc**

**ISO/CD 8536-6 Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles** has been circulated as a committee draft for voting until 15 October.

**ISO/CD 8871-5 Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing** has been circulated for voting until 15 October.

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## **FINAL DRAFTS**

**ISO/FDIS 17665:2023 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices** has been circulated for formal vote until 2 November.

**FprCEN/TS 17981-1 In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human DNA examination** has been approved by national members.

**FprCEN/TS 17981-2 In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 2: Human RNA examination** has been approved by national members.

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## **STANDARDS OUT FOR REVIEW**

EN 15154-1:2006 Emergency safety showers - Part 1: Plumbed-in body showers for laboratories.

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## **STANDARDS RECONFIRMED**

ISO 21501-4:2018 (Ed 2) Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces.

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## **STANDARDS APPROVED**

None

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## **STANDARDS PUBLISHED**

BS EN ISO 10991:2023 - Microfluidics. Vocabulary.

BS ISO 13319-2:2023 Determination of particle size distribution — Electrical sensing zone method Part 2: Tunable resistive pulse sensing method.

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## **STANDARDS WITHDRAWN**

None