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L@b Brief Standards Newsletter – March 2025

NEW WORK ITEMS PROPOSED

ISO 17849 PWI Medical Laboratories: Guidance on the validation and verification of quantitative and qualitative examination methods

ISO/PWI 22546 Laboratory design — Concept and principles

ISO/PWI TS 25646 In vitro diagnostic medical devices — Definition of analytical performance specifications for laboratory measurements based on medical requirements

ISO/PWI TS 25725 Design and workflow requirements for NGS-based oncology application

ISO/NP 25753 - Laboratory design — Smart laboratory design — General requirements

ISO/NP 25754 - Laboratory design — Smart laboratory design — Dairy products requirements

NEW WORK ITEMS ACCEPTED

N 1359 'Characterization of liquid dispersion homogeneity'

Adaption of NWI for EN 14056-5 Laboratory furniture - Recommendations for design and installation - Part 5: Services distribution carriers

ISO/NP PWI TS 20327, Packaging for terminally sterilized devices — Receiving, handling, transporting, distributing and storing of packaged sterile medical devices under the control of health care facilities

EN ISO 25379-1, In vitro diagnostic Next Generation Sequencing (NGS) workflows -- Part 1: Human DNA examination revision and transfer to ISO level of CEN/TS 17981-1 with the same title

EN ISO 25379-2, In vitro diagnostic Next Generation Sequencing (NGS) workflows -- Part 2: Human RNA examination the revision and transfer to ISO level of CEN/TS 17981-2 with the same title.

DRAFT STANDARDS

ISO/DIS 9276-1 ‘Representation of results of particle size analysis — Part 1: Graphical representation’ was approved but comments need to be taken in before it goes to FDIS.

ISO/DIS 11040-3 (Ed 3) Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges

ISO/CD 11138-6.2, Sterilization of health care products — Biological indicators — Part 6: Biological indicators for hydrogen peroxide sterilization processes

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ISO/CD 11737-1.2 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

ISO 15198:2004 Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer

ISO/DIS 15883-6:2025 Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for noncritical medical devices and health care equipment

prEN 17180 Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing

ISO/CD 19253.2 Sterilization of health care products — Moist heat — Requirements for sterilizers used for the terminal sterilization of aqueous liquid in sealed containers

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

ISO/DIS 22412 (Ed 3)Particle size analysis — Dynamic light scattering (DLS)

ISO/DIS 22544 Laboratory design — Vocabulary

ISO/CD 24051-1 Medical laboratories — Part 1: General principles for the application of artificial intelligence in medical laboratories

ISO/CD 24645 General requirements for Luer activated needle-free connectors (LANCs) for intravascular applications

ISO/CD TS 24883 CD Consultation ballot for Lateral flow immunoassay for rapid diagnostic testing-General guidance for test performance.

FINAL DRAFTS CIRCULATED

ISO/FDIS 1135-4 (Ed 7) Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed

ISO/FDIS 1135-5 (Ed 2) Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus

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STANDARDS OUT FOR REVIEW

BS 593:1989 for Confirmation (2025 review) Specification for laboratory thermometers

BS 1428-D4:1963 for Reconfirmation (2025 review) Microchemical apparatus. Volumetric analysis -- Specification for capillary pipettes

BS 2975-1:2004 for Reconfirmation (2025 review) Sampling and analysis of glass-making sands -- Methods for sampling and physical testing of glass-making sands

BS 3996:1978 for Confirmation (2025 review) Specification for colour coding for one-mark and graduated pipettes (including requirements for the service performance of the colour coding enamels)

BS 5248:1990 for Reconfirmation (2025 review) Specification for aspirated hygrometer

BS 5471:1977 for Confirmation (2025 review) Specification for thermometer for use with alcohol hydrometers

ISO 8871-3:2003 (vers 4) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count a majority voted to confirm rather than revise this document but only 5 to 4.

ISO 11737-2 Sterilization of health care products – Microbiological methods – Part 2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process a majority voted to confirm rather than revise this document 14 to 5.

ISO 13408-4:2005 (vers 4) Aseptic processing of health care products - Part 4: Clean-in-place technologies a majority voted to confirm rather than revise this document 10 to 4.

EN 15154-3, Emergency safety showers - Part 3: Non plumbed-in body showers

EN 15154-4, Emergency safety showers - Part 4: Non plumbed-in eyewash units.

STANDARDS RECONFIRMED

ISO 8536-3:2009 (Ed 3, vers 3) Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles

ISO 8536-7:2009 (Ed 3, vers 3) Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles

ISO 15137:2005 (vers 4) Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods

EN 15154-6, Emergency safety showers - Part 6: Plumbed-in multiple nozzle body showers for sites other than laboratories

ISO/TS 16775 Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2

ISO 21501-3:2019 Determination of particle size distribution — Single particle light interaction methods — Part 3: Light extinction liquid-borne particle counter

ISO/TS 22107:2021 Dispersibility of solid particles into a liquid

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STANDARDS APPROVED

FprEN 868-2 Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

FprEN 868-3 Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods

FprEN 868-4 Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

FprEN 868-6 Packaging for terminally sterilized medical devices - Part 6: Paper for low temperature sterilization processes - Requirements and test methods

FprEN 868-7 Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods

FprEN ISO 8871-5 Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing

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

FprEN ISO 15883-7 Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment

STANDARDS PUBLISHED

BS EN 14175-1:2003 - Fume cupboards. Vocabulary

BS EN 14175-2:2003 - Fume cupboards. Safety and performance requirements

BS EN 14175-3:2019 - Fume cupboards. Type test methods

BS EN 14175-4:2004 - Fume cupboards. On-site test methods

BS EN 14175-6:2006 - Fume cupboards. Variable air volume fume cupboards

DD CEN/TS 14175-5:2006 - Fume cupboards. Recommendations for installation and maintenance

BS EN ISO 15883-1:2025 - Washer-disinfectors. General requirements, terms and definitions and tests

BS EN ISO 15883-2:2025 - Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

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BS EN ISO 15883-3:2025 - Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

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STANDARDS WITHDRAWN

ISO 15198:2004 Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer

ISO 18153:2003 in vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials