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L@b Brief Standards Newsletter – March 2026

NEW WORK ITEMS PROPOSED

PNW TS 85-991 ED1: Laboratory Electromagnetic Equipment Data Exchange Interface

NWIP 130-51 ED1: Cold storage equipment for medical use - Part 2-2: Cryogenic liquid nitrogen storage equipment - Performance requirements and test methods. This item is open for public comment, you can register to comment here.

ISO/PWI TS 24069 Medical laboratories — Guidance for personnel competence and development

ISO/PWI 26358 In vitro diagnostic medical devices — Performance evaluation — Requirements and guidance

NEW WORK ITEMS ACCEPTED

NWIP CEN_TS pre-exam infectious pathogens

PWI - EN 285 for the revision of an EN 285:2015+A1:2021 Large steam sterilizers

ISO 385:1977 Hydrometers Principles of construction and adjustment (revision)

PAS 3500: Requirements for DNA bar coding of engineered biological assets - Specification

PAS 6543 Announcement of new work: Recycled plastics – Laboratory and medical products– Code of practice

ISO/AWI 26358 : In vitro diagnostic medical devices — Performance evaluation — Requirements and guidance

DRAFT STANDARDS

ISO/CD 695 Glass — Resistance to attack by a boiling aqueous solution of mixed alkali — Method of test and classification

prEN 868-5 Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels constructed of porous materials and plastic film - Requirements and test methods

prEN 868-8 Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

prEN 868-9 Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods

prEN 868-10 Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefins - Requirements and test methods

ISO/DIS 1776 (Ed 2) Glass — Resistance to attack by hydrochloric acid at 100°C — Flame emission or flame atomic absorption spectrometric method

ISO/DIS 3826-2 (Ed 2) Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets

ISO/DIS 3826-3 (Ed 2) Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems and its integrated features

ISO/DIS 3826-4 (Ed 2) Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features

ISO/TS 5798:2022: In vitro diagnostic test systems — Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods

ISO/CD TS 8219: Sequencing and clinical application to infectious diseases has been circulated for comment.

ISO 11040-8 - Form 13 Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes has been approved as an enquiry draft

ISO/DIS 11737-1:2026Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

ISO 11737-3:2023 Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing

ISO 13408-2:2018/DAmd1 Aseptic processing of health care products – Part 2 Sterilising filtration – Amendment 1 has been approved at enquiry stage

prEN 14056-5 Laboratory furniture - Recommendations for design and installation - Part 5: Services distribution carriers

prEN 15154-3 Emergency safety showers - Part 3: Non plumbed-in body showers has been approved at enquiry level

prEN 15154-4 Emergency safety showers - Part 4: Non plumbed-in eyewash units has been approved at enquiry level.

ISO/CD 15197: In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

ISO 17511:2020 : In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

ISO/DTS 17664-3 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

ISO/DIS 19253 Sterilization of health care products — Moist heat — Requirements for sterilizers used for the terminal sterilization of aqueous liquid in sealed containers

ISO/CD TS 19997 Guidelines for good practices in zeta-potential measurement

ISO 21151:2020 : In vitro diagnostic medical devices — Requirements for international harmonisation protocols establishing metrological traceability of values assigned to calibrators and human samples

ISO/CD TS 21385 Guidance for emerging technologies intended for medical laboratory use

ISO 21474-1:2020 : In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 1: Terminology and general requirements for nucleic acid quality evaluation

ISO/CD 21881 Sterile packaged ready for filling glass cartridges

ISO/CD 21882 Sterile packaged ready for filling glass vials

ISO/CD 22916 Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

ISO/DIS 24051-1 Medical laboratories — Part 1: General principles for the application of artificial intelligence in medical laboratories has been circulated for comment.

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

ISO/CD 25224.2 Sterilization of health care products — Sampling and culturing for reusable, thermolabile flexible endoscopes

ISO/CD 25459: In vitro diagnostic medical devices — Requirements for determining commutability of certified reference materials used as secondary calibrators or trueness controls – a majority approved this draft to go to DIS stage.

FINAL DRAFTS CIRCULATED

ISO 385:1977 Hydrometers Principles of construction and adjustment

ISO/FDIS 11040-8 (Ed 2) Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes

ISO/DIS 13926-2 (Ed 4) Pen systems — Part 2: Plunger stoppers for cartridge-type needle-based injection systems (NIS) for medical use

prEN 15154-4 Emergency safety showers - Part 4: Non plumbed-in eyewash units

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ISO/FDIS 15747 (Ed 4) Plastic containers for intravenous injections

ISO/DTS 17664-3:2026 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

FprEN ISO 22367 Medical laboratories - Application of risk management to medical laboratories

ISO/FDIS 22367 (Ed 2) Medical laboratories — Application of risk management to medical laboratories

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STANDARDS OUT FOR REVIEW

BS 572:1985 for Reconfirmation (2026 review) Specification for interchangeable conical ground glass joints

BS 894:1956 for Reconfirmation (2026 review) Specification for Ubbelohde apparatus for flow and drop points

BS 1132:1987 for Reconfirmation (2026 review) Specification for automatic pipettes

BS 1922:1987+A2:2011 for Reconfirmation (2026 review) Specification for glass dispensing measures for pharmaceutical purposes

BS 2646-1:2021 for Confirmation (2026 review) Autoclaves for sterilization in laboratories -- Design, construction, safety and performance. Specification

BS 2648:1955 for Reconfirmation (2026 review) Performance requirements for electrically-heated laboratory drying ovens

BS 3693:1992 for Reconfirmation (2026 review) Recommendations for design of scales and indexes on analogue indicating instruments

BS 4309:1968 for Reconfirmation (2026 review) Methods of measuring the performance of laboratory electric resistance furnaces

BS 5732:1985 for Reconfirmation (2026 review) Specification for glass disposable Pasteur pipettes

BS 6256:2021 for Confirmation (2026 review) Packaging for terminally-sterilized medical devices. Method for determination of methylene blue particulate penetration

BS 6706:1986 for Reconfirmation (2026 review) Specification for disposable glass serological pipettes

BS 7194:1990 for Reconfirmation (2026 review) Specification for direct-current and low-frequency electronic measuring instruments with a digital display

ISO/DIS 11040-5 (Ed 4) Prefilled syringes — Part 5: Plunger stoppers for injectables

ISO 13408-4:2005 Aseptic processing of health care products — Part 4: Cleaning processes for surfaces used within a critical processing zone (revised scope)

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ISO 14937:2009: Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes

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STANDARDS RECONFIRMED

ISO/TS 5111:2022 Guidance on quality of water for sterilizers

ISO 17867:2020 (Ed 2) Particle size analysis — Small angle X-ray scattering (SAXS)

STANDARDS APPROVED

None

STANDARDS PUBLISHED

PAS 2090: New standard to support pharmaceutical sustainability and transparency BS EN ISO 15883-6:2026 - Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-critical medical devices and health care equipment

PD ISO/TS 7446:2026 - Implementation guidance for biorisk management for laboratories and other related organizations

BS EN ISO 18704:2026 - Molecular in vitro diagnostic examinations — Requirements and recommendations for preexamination processes for urine and other body fluids — Isolated cell-free DNA

STANDARDS WITHDRAWN

None