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L@b Brief Standards Newsletter – May 2024

Moist heat sterilisation
BS EN ISO 17665:2024 Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices has been published by BSI who are drawing it to the attention of those who might be interested. You can find the linked in post here, an executive briefing here and the BSI shop here.

MDR and IVDR
It is likely that a request for a draft amendment to standardise the MDR-IVDR in support of Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU)2017/746 on In Vitro Diagnostic Medical Devices (IVDR) will be approved.
A draft request has already been approved and according to the EU, it intends to extend the M/575 validity date to December 2028 and improve other parts of M/575 including the Recitals, Articles and Annex III Requirements.

NEW WORK ITEMS PROPOSED

ISO/NP 11138-6 specifies requirements for test organisms, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilizers and sterilization processes employing vaporized hydrogen peroxide as the sterilizing agent.

ISO/NP TS 19673 'Particle characterization — Colour image analysis methods

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

ISO/NP 25224 Sterilization of health care products — Sampling and culturing for reusable, thermolabile flexible endoscopes

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NEW WORK ITEMS ACCEPTED

NWI for EN 16589-2 Laboratory local exhaust devices Part 2: Commissioning and Onsite Testing.

DRAFT STANDARDS

ISO/DTR 6037 Automated liquid handling systems – Uncertainty of the measurement procedures was approved.

ISO/DTS 6417 Microfluidic pumps — Symbols and performance communication has been circulated for approval.

ISO/DIS 8536-6 (Ed 4) Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles has been circulated for technical comment.

ISO 8655-7:2022/DAmd 1 (Ed 2) Piston-operated volumetric apparatus — Part 7: Alternative measurement procedures for the determination of volume — Amendment 1 has been approved at enquiry stage but 1 was disapproved at CEN ballot.

ISO/DIS 8871-5 (Ed 3) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing has been circulated for technical comment.

ISO/CD 9276-1 Representation of results of particle size analysis — Part 1: Graphical representation, has been circulated for national vote.

ISO/CD 11138-6 Sterilization of health care products — Biological indicators — Part 6: Biological indicators for hydrogen peroxide sterilization processes has been circulated for national vote.

ISO/DIS 15883-7 (Ed 2) Committee ISO/TC 198 Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment has been approved at enquiry stage

ISO/CD 11737-1 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products has been circulated as a committee draft.

ISO/DIS 18472 (Ed 2) Sterilization of health care products -- Biological and chemical indicators -- Test equipment has been approved at enquiry stage

ISO/DIS 22412 (Ed 3) Particle size analysis — Dynamic light scattering (DLS) a draft has been circulated for comment.

FINAL DRAFTS

FprEN 556-1 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices has been approved for publication..

ISO/FDIS 15883-1:2024 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests.

ISO/FDIS 19430 (Ed 2)Determination of particle size distribution and number concentration by particle tracking analysis (PTA) has been circulated for final vote.

IEC 62974-1 ED2: Monitoring and measuring systems used for data collection, aggregation and analysis - Part 1: Device requirements has been circulated for approval to publish.

STANDARDS OUT FOR REVIEW

EN 1659:1996 In vitro diagnostic systems - Culture media for microbiology - Terms and definitions.

ISO 11418-4:2005 (Ed 2, vers 4) Containers and accessories for pharmaceutical preparations — Part 4: Tablet glass bottles.

ISO 12154:2014 (vers 2) Determination of density by volumetric displacement — Skeleton density by gas pycnometry.

EN 12322:1999 In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media.

EN 13792-2002 Colour coding of taps and valves for use in laboratories.

ISO 13926-3:2019 (Ed 2) Pen systems — Part 3: Seals for pen-injectors for medical use.

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

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

ISO 15759:2005 (Ed 2, vers 4) Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process.

ISO/TS 16782:2016 (vers 2) Clinical laboratory testing — Criteria for acceptable lots of dehydrated Mueller-Hinton agar and broth for antimicrobial susceptibility testing.

ISO 18153:2003 (vers 4) 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.

ISO 20776-1:2019 (Ed 2) Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases.

ISO 20916:2019 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice.

ISO 21882:2019 Sterile packaged ready for filling glass cartridges.

STANDARDS RECONFIRMED

None

STANDARDS APPROVED

None

STANDARDS PUBLISHED

PD ISO/TS 5441:2024 - Competence requirements for bio-risk management advisors.

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PD ISO/TR 6037:2024 - Automated liquid handling systems. Uncertainty of the measurement procedures.

BS EN ISO 11607-1:2020 +A1:2023 - Packaging for terminally sterilized medical devices. Part 1. Requirements for materials, sterile barrier systems and packaging systems.

BS ISO 13317-1:2024 - Determination of particle size distribution by gravitational liquid sedimentation methods. General principles, requirements and guidance.

BS EN ISO 13408-1:2024 - Aseptic processing of health care products. General requirements.

STANDARDS WITHDRAWN
None