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L@b Brief Standards Newsletter – April 2025

UK expert Richard Bancroft has been appointed chair of CEN/TC 204 which works on sterilisation of medical devices.

NEW WORK ITEMS PROPOSED

Activation of PWI for EN 14175-9, Fume cupboards — Part 9: Fume cupboards, ducted with filtered internal recirculation, it is likely that the UK will vote in favour of this proposal.

ISO/PWI 22546 Laboratory design — Concept and principles.

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

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

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

ISO/NP TS 25887 Sterilization of health care products — Microbiological methods — Bacterial endotoxin testing — Use of recombinant animal-free reagents.

NEW WORK ITEMS ACCEPTED

None

DRAFT STANDARDS

ISO/DIS 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric infusion controllers has been approved to move to FDIS stage.

FprEN 13060 Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing is out for voting until 10 May.

ISO/DIS 13099-2 (Ed 2) Colloidal systems — Methods for zeta-potential determination — Part 2: Optical methods. It has been agreed that as there were no comments this standard will be published without going to FDIS stage.

ISO/CD 13926-1, Cartridge systems — Part 1: Glass cylinders for cartridge-type needle-based injection systems for medical use.

ISO/CD 15883-4 Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

ISO/DIS 15883-6 (Ed 2) Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for noncritical medical devices and health care equipment.

ISO/CD 19676 'Single particle light interaction methods — Bio-fluorescence airborne particle counter for clean spaces. This draft has received comments at committee stage.

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

ISO/DIS 22544 Laboratory design — Vocabulary.

ISO/DIS 22637:2025 Medical laboratories - Application of risk management to medical laboratories. This draft has been circulated at enquiry stage.

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

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.

FprEN 13060, Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing, has been circulated for formal vote. Voting is open until 22 May.

STANDARDS OUT FOR REVIEW

ISO 695:1991 (Ed 3, vers 6) Glass — Resistance to attack by a boiling aqueous solution of mixed alkali — Method of test and classification.

ISO 4142:2002 (Ed 2, vers 4) Laboratory glassware — Test tubes.

ISO/TS 4807:2022 Reference materials for particle size measurement — Specification of requirements.

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 8536-10:2015 (Ed 2, vers 2) Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment.

ISO 8362-7:2006 (Ed 2, vers 4) Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part.

ISO 8871-2:2020 (Ed 2) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterisation.

ISO 8871-4:2006 (vers 4) Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods.

ISO 9276-5:2005 (vers 4) Representation of results of particle size analysis — Part 5: Methods of calculation relating to particle size analyses using logarithmic normal probability distribution.

ISO 13317-4:2014 (vers 2) Determination of particle size distribution by gravitational liquid sedimentation methods — Part 4: Balance method.

ISO 13318-3:2004 (vers 4) Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 3: Centrifugal X-ray method.

ISO 13320:2020 (Ed 2) Particle size analysis — Laser diffraction methods.

EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing.

EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices.

EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents.

EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects.

EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures.

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

EN 15154-5:2019 Emergency safety showers - Part 5: Water overhead body showers for sites other than laboratories.

ISO 15190:2020 (Ed 2) Medical laboratories — Requirements for safety.

CEN/TS 17688-1:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 1: Isolated cellular RNA.

CEN/TS 17688-2:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 2: Isolated proteins.

CEN/TS 17688-3:2021 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 3: Isolated genomic DNA.

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 27891:2015 (vers 2) Aerosol particle number concentration — Calibration of condensation particle counters

ISO 28620:2020 (Ed 2) Medical devices — Non-electrically driven portable infusion devices.

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STANDARDS RECONFIRMED

BS 593:1989 Specification for laboratory thermometers.

BS 1428-D4:1963 Microchemical apparatus. Volumetric analysis -- Specification for capillary pipettes.

BS 2975-1:2004 Sampling and analysis of glass-making sands – Methods for sampling and physical testing of glass-making sands.

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

BS 5248:1990 Specification for aspirated hygrometer.

BS 5471:1977 Specification for thermometer for use with alcohol hydrometers.

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS ISO 8536-6:2025 - Infusion equipment for medical use. Freeze drying closures for infusion bottles.

BS EN ISO 8871-5:2025 - Elastomeric parts for parenterals and for devices for pharmaceutical use. Functional requirements and testing.

BS EN 14180:2025 - Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers. Requirements and testing.

STANDARDS WITHDRAWN

None