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L@b Brief Standards Newsletter – July 2025

Congratulations to GAMBICA's own Richard Manford who has been appointed convenor of CEN/TC 102/WG 8 "Washer disinfectors" for a period of 6 years starting on 2025-08 04. Richard works for Steris.

NEW WORK ITEMS PROPOSED

PWI for EN 12469-3 Biological safety cabinets — Part 3: BSC class III

EN 12469-4, Biological safety cabinets — Part 4: BSC class I

ISO/PWI 22064 Determination of core radius and shell thickness of spherical core-shell particles by small-angle X-ray scattering (SAXS)

ISO/PWI 25816 Direct shear test method for determination of the critical state line (CSL) and wall yield locus (WYL) of a powder bed

ISO/NP 25992 - Single-use receptacles for human arterial blood specimen collection（arterial blood gas collection needles）

ISO/NP TS 26031 - Laboratory design — Mobile laboratories — Classification

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NEW WORK ITEMS ACCEPTED

N 145 Laboratory design

NW TS 62A-1648 ED1: Medical devices – Part 3: Guidance on the application of usability engineering to medical devices using artificial intelligence and machine learning technology

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

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DRAFT STANDARDS

ISO/TC 209 Cleanrooms and associated controlled environments.

ISO 719:2020 (Ed 3) Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification

ISO 720:2020 (Ed 3) Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification

prEN 1422 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods has been approved at enquiry stage.

ISO/CD 8536-5 Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed

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

ISO/DIS 11135:2025 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO/DIS 11607-3 : Packaging for terminally sterilized medical devices — Part 3: Requirements for process development for forming, sealing and assembly

FprEN 12469-1 Biological safety cabinets - Part 1: Classes and basic requirements

FprEN 12469-2 Biological safety cabinets - Part 2: BSC class II

FprEN 12469-5 Biological safety cabinets - Part 5: Installation, commissioning and routine testing

FprEN 13060 Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing has been approved at National Vote.

ISO/DIS 13926-1 (Ed 5) Cartridge systems — Part 1: Glass cylinders for cartridge-type needle-based injection systems (NIS) for medical use

ISO 14160:2020 (Ed 3) Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices

ISO 14411-2:2020 Preparation of particulate reference materials — Part 2: Polydisperse spherical particles

ISO 14644-7 Cleanrooms and associated controlled environments — Part 7: Separative devices has been circulated as a working group consultation.

ISO 15212-1:1998 (vers 5) Oscillation-type density meters — Part 1: Laboratory instruments

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

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

prEN 16589-2 Laboratory local exhaust devices - Articulated extraction arms - Part 2: Commissioning and on-site testing

FprEN 17242 Recirculatory Filtration Fume Cabinets

ISO/CD TS 18196 'Nanotechnologies — Measurement technique matrix for the characterization of nano-objects' – Invitation to comment

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/DIS 22367 (Ed 2) Medical laboratories — Application of risk management to medical laboratories was approved at enquiry stage.

ISO/CD 24051-1.2 Medical laboratories — Part 1: General principles for the application of artificial intelligence in medical laboratories has been circulated a second time as a committee draft.

ISO/CD 25459 In vitro diagnostic medical devices — Requirements for determining commutability of certified reference materials used as secondary calibrators or trueness controls

62A/1675/CD IEC 60601-1/FRAG5 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - PEMS related hazards (Fragment 5)

62A/1676/CD IEC 60601-1/FRAG6 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electrical hazards (Fragment 6)

62A/1677/CD IEC 60601-1/FRAG7 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Mechanical hazards (Fragment 7)

IEC 62A/1673/CD IEC 60601-1/FRAG8 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Thermal and fire hazards (Fragment 8)

62A/1671/CD - IEC 60601-1/FRAG10 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Ionizing radiation hazards (Fragment 10)

IEC 60601-1/FRAG11 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic exposure hazards (Fragment 11) has been circulated for an internal National Committee ballot.

62A/1672/CD - IEC 60601-1/FRAG12 ED4: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic disturbances hazards (Fragment 12)

IEC 61010-1/AMD2 ED3: Amendment 2 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements has been rejected at committee draft stage.

FINAL DRAFTS CIRCULATED

ISO/FDIS 8536-16 Infusion equipment for medical use — Part 16: Infusion sets for single use with volumetric

FprEN 14056-1 Laboratory furniture - Recommendations for design and installation - Part 1: General

ISO/FDIS 22412 (Ed 3) Particle size analysis — Dynamic light scattering (DLS)
infusion controllers, has been approved for publication

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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 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 8536-8:2015 (Ed 2, vers 2) Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus

ISO 8536-9:2015 (Ed 2, vers 2) Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment

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

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 11418-5:2015 (Ed 2, vers 2) Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies

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

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

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

ISO 17511:2020 (Ed 2) In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

ISO/CD TS 19673 Particle characterization — Colour image analysis methods

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

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STANDARDS RECONFIRMED

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

ISO 13320:2020 Particle size analysis — Laser diffraction methods

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

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STANDARDS APPROVED

None

STANDARDS PUBLISHED

PD ISO/TS 6417:2025 - Microfluidic pumps — Symbols and performance communication

BS EN ISO 22916:2022 - Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

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STANDARDS WITHDRAWN

None