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L@b Brief Standards Newsletter – July and August 2022

The following standards are to be designated under the Electrical Equipment (Safety) Regulations 2016

EN 60898-2:2021 - Electrical accessories – Circuit-breakers for overcurrent protection for household and similar installations – Part 2: Circuit-breakers for a.c. and d.c. operation

EN IEC 61010-2-030:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-030: Particular requirements for equipment having testing or measuring circuits

EN IEC 61010-2-034:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-034: Particular requirements for measurement equipment for insulation resistance and test equipment for electric strength

EN IEC 61010-2-061:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-061: Particular requirements for laboratory atomic spectrometers with thermal atomization and ionization

EN IEC 61010-2-051:2021/A11:2021 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-051: Particular requirements for laboratory equipment for mixing and stirring

EN IEC 61010-2-130:2021 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-130: Particular requirements for equipment intended to be used in educational establishments by children

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NEW WORK ITEMS PROPOSED

Electrical

PNW 47-2773 ED1: Semiconductor devices - Isolation for semiconductor devices. Part 1: Failure mechanisms and measurement methods to evaluate solid insulation for semiconductor devices.

PNW 23E-1272 ED1: IEC 61009-3: Residual current operated circuit-breakers with integral overcurrent protection for household and similar uses (RCBOs) - part 3 Semiconductor RCBOs.

STERILISING

N776 Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.

IVDs etc

ISO/NP TS 18702 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood — DNA, RNA and proteins – closes 4th September.

ISO/NP 18703 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Isolated circulating cell free RNA from plasma – voting to approve this new work item closes 4th September.

ISO/NP 18704 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for urine and other body fluids — Isolated cell free DNA – also closes 4th September.

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ISO/NP TS 18701 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for human specimens — Isolated microbiome DNA – closes 4th September.

NEW WORK ITEMS ACCEPTED

PWI TR 24327 Guidelines for acoustic measurements of rheological properties.

NP TS 16766, Considerations for manufacturers for in vitro diagnostic medical devices during a public health crisis

Adoption of ISO 4803:2021 Laboratory glassware — Borosilicate glass tubing as a EN ISO standard.

STANDARDS TO BE REVISED OR OUT FOR REVIEW

ELECTRICAL

ISO 22412:2017 Particle size analysis — Dynamic light scattering (DLS) a proposal to revise this document has been approved.

PARTICLE CHARACTERISATION

ISO 4783-2 : 1989 Industrial wire screens and woven wire cloth - Guide to the choice of aperture size and wire diameter combinations - Part 2- Preferred combinations for woven wire cloth.

ISO 10630 : 1994 Industrial plate screens - Specifications and test methods.

ISO/DIS 20998-2 (Ed 2) Measurement and characterization of particles by acoustic methods — Part 2: Guidelines for linear theory is out for voting until 5 October.

ISO 9276-3: 2008 Representation of results of particle size analysis - Part 3- Adjustment of an experimental curve to a reference model.

ISO 20998-3 : 2017 Measurement and characterization of particles by acoustic methods - Part 3- Guidelines for non-linear theory.

ISO 22412:2017 Particle size analysis — Dynamic light scattering (DLS) has been approved for revision.

ISO 13099-1:2012 (vers 2) Colloidal systems — Methods for zeta-potential determination — Part 1: Electroacoustic and electrokinetic phenomena.

ISO 13099-2:2012 (vers 2) Colloidal systems — Methods for zeta-potential determination — Part 2: Optical methods.

STERILISING

ISO 11138-1:2017 Sterilization of health care products — Biological indicators — Part 1: General requirements – systematic review closes on 18th October.

ISO 11138-2:2017 Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes - closes on 18th October

IVDs etc

EN 13532:2002, General requirements for in vitro diagnostic medical devices for self-testing is to be reviewed as due to the age of the standard, a revision of Annex Z alone is not possible without a revision of the standard itself ballot closes on 4 October.

EN 13612:2002, Performance evaluation of in vitro diagnostic medical devices is also to be reviewed, ballot closes on 4 October.

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

EN 13975:2003, Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspect, ballot on the revision of this standard closes on 4 October.

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

GENERAL LAB

ISO 6152:1982 Thermometers for use with alcoholometers and alcohol hydrometers has been recommended for withdrawal.

ISO 4796-2:2000 (vers 4) Laboratory glassware — Bottles — Part 2: Conical neck bottles.

ISO 835:2007 (vers 3) Laboratory glassware — Graduated pipettes.

ISO 13079:2011 (vers 2) Laboratory glass and plastics ware — Tubes for the measurement of the erythrocyte sedimentation rate by the Westergren method.

ISO 22870:2016 Ed 2 Point-of-care testing (POCT) — Requirements for quality and competence it has been agreed that this will be superseded by ISO 15189 once the next edition of ISO 15189 is published

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DRAFT STANDARDS

LAB GENERAL

prEN ISO 10991 Microfluidics - Vocabulary (ISO/DIS 10991:2022) is out for voting until 10 October.

ISO/DIS 13132:2022 Laboratory glassware - Petri dishes has been circulated for voting at enquiry stage.

ISO/DIS 20658 Medical laboratories — Requirements for collection and transport of samples is out for voting until 21 September.

ISO 3826-1:2019/DAM 1 Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers — Amendment 1.

STERILISING

ISO/CD 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices is out for voting until 16 October.

ISO/CD 11137-1, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices Is out for voting until 7 October.

ISO 11139:2018/CD Amd 1 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Amendment 1 has been approved for circulation as a DIS.

EN ISO 11607-1/prA1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging - Amendment 1 is out for voting at parallel enquiry stage until 25 October.

EN ISO 11607-2/prA1, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1 is out for voting at parallel enquiry stage until 25 October.

PARTICLE CHARACTERISATION

ISO/DIS 13319-2 Determination of particle size distribution — Electrical sensing zone method — Part 2: Tuneable resistive pulse sensing method – was approved at DIS stage

ISO/DIS 26824 (Ed 2) Particle characterization of particulate systems — Has been approved for circulation as an FDIS.

IVDs etc

ISO 8536-15:2022 Amd 1, Infusion equipment for medical use — Part 15: Light-protective infusion sets N 1537 has been approved for circulation as a DIS.

Current use + harmonization of EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing – closes 20th September.

Current use + harmonization of EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices – closes 20th September.

Current use + harmonization of EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents – closes 20th September.

Current use + harmonization of EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects – closes 20th September.

Current use + harmonization of EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures – closes 20th September.

prEN IEC 61010-2-101:2022/FprAA - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment has been circulated for vote to proceed to publication.

ELECTRICAL

EN 60898-1:2019 prA1 Electrical accessories - Circuit-breakers for overcurrent protection for household and similar installations - Part 1: Circuit-breakers for a.c. operation (IEC 60898-1:2015/AMD1:2019) has been circulated for voting at enquiry stage.

EN 60898-1:2019 prAA Electrical accessories - Circuit-breakers for overcurrent protection for household and similar installations - Part 1: Circuitbreakers for a.c. operation is out for voting at enquiry stage until 9 September.

IEC 61010-031 ED3: Safety requirements for electrical equipment for measurement, control and laboratory use – Part 031: Safety requirements for hand-held and hand-manipulated probe assemblies for electrical test and measurement has been approved for registration as an FDIS.

IEC 61010-2-034 ED2: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-034: Particular requirements for measurement equipment for insulation resistance and test equipment for electric strength has been approved for circulation as an FDIS.

IEC 61557-13 ED2 Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. - Equipment for testing, measuring or monitoring of protective measures - Part 13: Hand-held and hand-manipulated current clamps and sensors for measurement of leakage currents in electrical distribution systems committee draft circulated for vote which closes 23 September.

IEC 61558-2-10:2014 ED1 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-10: Particular requirements and tests for separating transformers with high insulation level and separating transformers with output voltages exceeding 1 000 V has been circulated for voting as a committee draft.

IEC 61558-2-20 ED3: Safety of transformers, reactors, power supply units and combinations thereof - Part 2-20: Particular requirements and tests for small reactors has been approved for circulation as an FDIS.

FINAL DRAFTS

ELECTRICAL

FDIS IEC 60755-1 ED1: General safety requirements for residual current operated protective devices - Part 1: Residual current operated protective devices is out for voting for approval to publish until 13 September.

prEN IEC 61010-2-101:2022/FprAA - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment has been circulated for approval to publish.

FDIS IEC 61543 ED2: Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility is out for vote until 20 September.

FDIS IEC 61558-2-2 ED3: Safety of transformers, reactors, power supply units and combinations thereof - Part 2-2: Particular requirements and tests for control transformers and power supply units incorporating control transformers is out for approval to publish until 9 September.

FDIS IEC 61558-2-13 ED3: Safety of transformers, reactors, power supply units and combinations thereof - Part 2-13: Particular requirements and tests for auto-transformers and power supply units incorporating auto-transformers for general applications is out for approval to publish until 9 September.

EN 62606:2013/FprAB General requirements for arc fault detection devices out for voting until 14 October.
FDIS IEC 62606/AMD2 ED1: Amendment 2 - General requirements for arc fault detection devices is out for voting until 20 September.

PARTICLE CHARACTERISATION

ISO/FDIS 20998-2 Measurement and characterization of particles by acoustic methods — Part 2: Linear theory' has been approved.

ISO/FDIS 26824 Particle characterization of particulate systems — Vocabulary has been approved for publication.

STERILISING

FprEN ISO/FDIS 11140-6, Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers is out for voting until 20 October.

ISO/FDIS 13004 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD has been circulated for ballot.

EN ISO 11607-1:2020/prA1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1 (ISO 11607-1:2019/DAM 1:2022) has been approved as a European Standard.

EN ISO 11607-2:2020/prA1 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1 (ISO 11607-2:2019/DAM 1:2022) has been approved as a European Standard.

IVDs etc

EN ISO 15197 In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus is out for revision of its Annex Z.

ISO/FDIS 18113-1 (Ed 2) In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements was circulated for voting. The vote has now closed.

ISO/FDIS 18113-2 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use.

ISO/FDIS 18113-3 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use.

ISO/FDIS 18113-4 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing.

ISO/FDIS 18113-5 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing.

ISO/FDIS 18113-5 (Ed 2) In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing were circulated for voting. The vote has now closed.

FprCEN ISO/TS 5798 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 is out for voting until 20 October.

LAB GENERAL

ISO/FDIS 15189 (Ed 4) Medical laboratories — Requirements for quality and competence is out for voting until 14 October.

STANDARDS RECONFIRMED

EN 12469:2000 - Biotechnology - Performance criteria for microbiological safety cabinets

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STANDARDS APPROVED

None

STANDARDS PUBLISHED

PAS 0:2022 *Principles of PAS standardization* and the release of BSI Flex 0 v2.0:2022-08 *Principles of BSI Flex standardization.* Free copies of these governance documents are available on the BSI website here

PD CEN/TS 17811:2022 Molecular in vitro diagnostic examinations. Specifications for pre-examination processes for urine and other body fluids. Isolated cell free DNA.

BS ISO 20804:2022 Determination of the specific surface area of porous and particulate systems by small-angle X-ray scattering (SAXS).

BS ISO 23783-1:2022 Automated liquid handling systems. Vocabulary and general requirements.

BS ISO 23783-3:2022 Automated liquid handling systems. Determination, specification and reporting of volumetric performance.

BS ISO 24166-1:2022 Snap-on bottles for metering pumps. Tubular glass.

BS ISO 24166-2:2022 Snap-on bottles for metering pumps. Moulded glass.

BS ISO 24166-3:2022 Snap-on bottles for metering pumps. Plastic.

BS EN ISO 25424:2019+A1:2022 Sterilization of health care products. Low temperature steam and formaldehyde. Requirements for development, validation and routine control of a sterilization process for medical devices

BS ISO 5215:2022 Laboratory plastic ware. Volumetric flasks.

BS EN IEC 60477-2:2022 Laboratory resistors. Laboratory AC resistors.

BS EN IEC 61557-12:2022+A1:2022 Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC. Equipment for testing, measuring or monitoring of protective measures. Power metering and monitoring devices (PMD).

BS EN ISO 8655-1:2002 Piston-operated volumetric apparatus. Terminology, general requirements and user recommendations.

BS EN ISO 8655-3:2022 Piston-operated volumetric apparatus. Burettes.

BS EN ISO 8655-6:2022 Piston-operated volumetric apparatus. Gravimetric reference measurement procedure for the determination of volume.

BS EN ISO 8655-7:2022 Piston-operated volumetric apparatus. Alternative measurement procedures for the determination of volume.

STANDARDS WITHDRAWN

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ISO 1768:1975 Glass hydrometers — Conventional value for the thermal cubic expansion coefficient (for use in the
preparation of measurement tables for liquids)

ISO 649-1:1981 Laboratory glassware — Density hydrometers for general purposes — Part 1: Specification
ISO 649-2:1981 Laboratory glassware — Density hydrometers for general purposes — Part 2: Test methods and use
ISO 4805:1982 Laboratory glassware — Thermo-alcoholometers and alcohol-thermohydrometers
ISO 650:1977 Relative density 60/60 degrees F hydrometers for general purposes
ISO 3507:1999 Laboratory glassware — Pyknometers

ENDS