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L@b Brief Standards Newsletter – March and April 2022

New PAS – bringing safe products to market
BSI has developed and published PAS 7050: Bringing safe products to the market. It aims to help firms to:

- ensure products comply with consumer safety product legislation;
- improve the efficiency with which safe products are brought to market;
- accelerate innovation and expertise in manufacturing;
- increase confidence of supply chain partners;
- reduce reputational, commercial and compliance risks.

Stainless steam boiler standard to be designated by UK
The UK government is considering designating the standard EN 14222:2021 - Stainless steel steam boilers on 21 May 2022. A designated standard is a standard which is recognised by government in part or in full as supporting CA Marking Regulations. Interested parties may object to a publication proposal within the 28-day timeframe by submitting an objection form to this email: designatedstandards@beis.gov.uk.
The objection must outline why the standard does not meet GB essential requirements either fully or partly. Please be aware, that BSI does not submit objections nor are any objections submitted on behalf of BSI committees. If you wish to submit any objections these are done in your own capacity or through your nominating organisations.

NEW WORK ITEMS PROPOSED

BS EN 556-1;2001 Sterilization of medical devices, this proposal for a new work item has been made available to the public by BSI. If you have not previously provided comments to BSI you will need to register on their portal here. To access the draft click here.

Similarly, **ISO/PWI TS 16766 - Manufacturers considerations for in vitro diagnostic medical devices in a public health crisis** is open for public comment as a proposed work item. Please register here if necessary and find the details of the standard here.

A proposal has been put by the Chinese National Committee to institute a new project committee on the **performance of cold storage equipment for medical use**. This is an updated proposal taking into account previous feedback. Comments on the latest proposal are invited.

prEN 16589-2 Laboratory local exhaust devices - Part 2: Commissioning and on-site testing has been proposed for review.

Guidance on the validation and verification of quantitative and qualitative methods.

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

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NEW WORK ITEMS ACCEPTED

Manufacturers' considerations for in vitro diagnostic medical devices in a public health crisis

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STANDARDS TO BE REVISED OR OUT FOR REVIEW

ISO 8536-15:2022 Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use has been circulated for a vote on amendment. The UK is likely to abstain.

EN 868-2, Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods
EN 868-3, Packaging for terminally sterilized medical devices — Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) — Requirements and test methods
EN 868-4, Packaging for terminally sterilized medical devices — Part 4: Paper bags — Requirements and test methods
EN 868-6, Packaging for terminally sterilized medical devices — Part 6: Paper for low temperature sterilization processes — Requirements and test methods and
EN 868-7, Packaging for terminally sterilized medical devices — Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods
are all out for systematic review until September.

ISO 11140-3:2007 & Cor.1:2007 'Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test'
ISO 11140-4:2007 'Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration'?
ISO 11140-5:2007 'Class 2 indicators for Bowie and Dick-type air removal tests'?
all three are currently out for voting on proposals to revise.

EN 13060:2014+A1:2018 small steam sterilizers is currently out for voting to be revised to meet the requirements of the new Medical Device Regulation (EU) 2017/745.

ISO 8536-14:2016 Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact has been confirmed at systematic review.

DRAFT STANDARDS

A draft BS ISO 13317-1 Determination of particle size distribution by gravitational liquid sedimentation methods. Part 1: General principles and guidelines has been loaded to the BSI Standards Development Portal for public comment. If you have not used the system before you will need to register here.
To view the draft click here.

A public draft is also available of **BS ISO 13319-2 Determination of particle size distribution - Electrical sensing zone method. - Part 2: Tuneable resistive pulse sensing method.** To comment register here and to view the document click here.

ISO/DIS 13319-2 – Determination of particle size distribution – Electrical sensing zone method – Part 2 Tuneable resistive pulse sensing method is out for voting until 12 June, the UK is likely to abstain.

ISO/CD 23484 Determination of particle concentration by small angle X-ray scattering (SAXS) has been approved and will now proceed to scrutiny as a DIS.

IEC 61010-031 ED3 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test is out for voting until 24 June.

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 is out for voting until 24 June.

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IEC 61010-2-203 ED1 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-203: Particular requirements for industrial communication circuits and communication port interconnection is out for voting until 10 May.

IEC 61540 ED2 Electrical accessories - Portable residual current devices without integral overcurrent protection for household and similar use (PRCDs) is out for voting as a committee draft until 3 June.

prEN 14175-8 Fume cupboards - Part 8: Fume cupboards for work with radioactive materials is out for formal vote with the UK likely to disapprove.

ISO/DTS 5111, Quality of water for sterilizers, sterilization and washer-disinfectors has been circulated for national vote on approval to publish. 13 countries agreed, UK abstained, Germany and Japan disapproved.

ISO/DIS 13408-1:2021 Aseptic processing of health care products - Part 1: General requirements has been approved by national vote at enquiry stage.

EN ISO 11607 Parts 1 and 2 Packaging for terminally sterilized medical devices. CEN/TC 102 proposes that the CEN technical board adopts the revised Annexes ZA and publishes these without delay, the UK is likely to abstain.

ISO/CD 11040-4 Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling is out for commenting and voting until 13 June.

ISO/CD 11040-7 Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling is also out for commenting and voting until 13 June.

ISO/CD 8536-2:2021(E) Infusion equipment for medical use — Part 2: Closures for infusion bottles this draft is out for voting until 1 June.

ISO/CD 8872:2021(E) Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods, this draft is out for voting until 1 June.

ISO/CD 4802-1:2022(E) Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification is out for voting at committee draft stage until 11 May.

ISO/CD 4802-2:2022(E)Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification this committee draft is out for voting until 11 May.

ISO 18362:2016/DAmd 1 Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1 – this amendment is to remove a normative reference to ISO 13485 in order to get acceptance from the HAS consultant for the adoption of the standard as an EN with a European annex Z. The UK is likely to approve.

ISO/DIS 24072 Aerosol bacterial retention test method for air-inlet on administration devices has been approved at a national vote on enquiry stage.

FprCEN/TS 17811 Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for urine and other body fluids - Isolated cell free DNA has been circulated for national vote.

FINAL DRAFTS

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 has been approved as an FDIS.

IEC 61558-2-4 ED3 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-4: Particular requirements and tests for isolating transformers and power supply units incorporating isolating transformers for general applications has been approved for publication.

IEC 61558-2-6 ED3 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-6: Particular requirements and tests for safety isolating transformers and power supply units incorporating safety isolating transformers for general applications has been approved for publication.

IEC 61558-2-15 ED3 Safety of transformers, reactors, power supply units and combinations thereof – Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations has been approved for publication as a national standard.

IEC 61340-2-1/AMD1 ED2 Amendment 1 - Electrostatics - Part 2-1: Measurement methods - Ability of materials and products to dissipate static electric charge (Proposed horizontal standard) has been approved for publication as an International Standard.

IEC 60477-1 ED1 Laboratory resistors - Part 1: Laboratory DC resistors has been approved for publication as an international standard.

IEC 60477-2 ED2 Laboratory resistors - Part 2: Laboratory AC resistors has been approved for publication as an international standard.

FprEN 14175-8 Fume cupboards - Part 8: Fume cupboards for work with radioactive materials has been circulated for final vote on approval to publish.

EN ISO 11607 Parts 1 and 2 Packaging for terminally sterilized medical devices. CEN/TC 102 proposes that the CEN technical board adopts the revised Annexes ZA and publishes these without delay. See the attached for more information, the UK is likely to approve this course of action.

ISO/FDIS 22441, Sterilization of health care products - Low temperature vaporized hydrogen peroxide Requirements for the development, validation and routine control of a sterilization process for medical is out for final approval to publish until 23 May.

ISO 11137-2:2013/FDAmd 1 (Ed 3), Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose - Amendment 1 UK is likely to approve this final draft.

ISO/FDIS 21474-2 In vitro diagnostic medical devices - Multiplex molecular testing for nucleic acids - Part 2-Validation and verification is out for approval to publish, UK is likely to approve.

STANDARDS RECONFIRMED

ISO 1135-3:2016 Transfusion equipment for medical use — Part 3: Blood-taking sets for single use

ISO 8536-1:2011 Infusion equipment for medical use — Part 1: Infusion glass bottles

ISO 8362-4:2011Injection containers and accessories — Part 4: Injection vials made of moulded glass

ISO 8536-14:2016 Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact

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STANDARDS APPROVED

ISO 8362-2:2015/DAM 1:2022 Injection containers and accessories - Part 2: Closures for injection vials – Amendment 1 Edition 3.

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STANDARDS PUBLISHED

BS ISO 13322-2:2021 Particle size analysis — Image analysis methods Part 2: Dynamic image analysis methods

BS EN ISO 8536-15:2022 Infusion equipment for medical use Part 15: Light-protective infusion sets for single use.

BS ISO 17593:2022 Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

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

STANDARDS WITHDRAWN

None

ENDS