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L@b Brief Standards Newsletter – July 2021

Hygiene and washer-disinfectors

During the development of **BS EN ISO 15883-5:2021 Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy**, repeated attempts were made to align the standard with the UK HTM residual protein requirements by modification to both the standard and the relevant HTMs. The committee was successful in getting a note added to the standard to highlight differences in measurements and is now discussing whether the national forward could be modified to further draw attention to the discrepancies or whether the NHS will issue a bulletin recognising the discrepancy and revising requirements to adhere to both cleanliness thresholds. In addition, the committee may look to place an article in one of the relevant journals to draw attention to the issue.

NEW WORK ITEMS PROPOSED

Some new work items have been loaded to the BSI Standards Development Portal for public comment in order to increase awareness of the Standards Development Portfolio. If you have not used the BSI commenting system before, you will need to register here.

ISO/PWI 5649 Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices (laboratory-developed tests). Please comment here.

ISO/NP 21474-3 In vitro diagnostic medical devices -- Multiplex molecular testing for nucleic acids -- Part 3: Interpretation and reports. Please comment here.

47/2713/NP: Semiconductor devices – Isolation technologies for semiconductor devices - Part 1: General requirement for supplementary, basic and reinforced solid insulation within semiconductor devices, standard technical SP is out for voting until 15 October.

ISO/PWI TS 23824 Guidance on application of ISO 15189 in anatomic pathology – this proposal is out to vote until 2nd September.

Risk Management of Particulate Contamination for devices with intravascular access has been circulated for comment is out for voting until 27 August, the UK is likely to approve.

NEW WORK ITEMS ACCEPTED

PNW 85-787 ED1: Electrical safety in low voltage distribution systems up to 1000V AC and 1500V DC Equipment for testing, measuring or monitoring protective measures, Part 18: DC EV Supply Equipment Monitoring Device

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STANDARDS TO BE REVISED OR OUT FOR REVIEW

None

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DRAFT STANDARDS

PAS 7050 Bringing safe products to market – code of practice has been circulated for comment.

IEC 60755-1 ED1 General safety requirements for residual current operated protective devices - Part 1: Residual current operated protective devices for DC systems is out for voting until firework night.

IEC 62606/AMD2 ED1 Amendment 2 - General requirements for arc fault detection devices is also out for voting until 5 November.

prEN IEC 60477-2 ED2 Laboratory resistors. Part 2: Laboratory AC resistors has been approved.

prEN IEC 60477 ED2 Laboratory DC resistors was also approved.

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 22 October.

EN IEC 61010-2-033:2021/A11:202X Safety of measuring, control, and laboratory equipment Annexes ZZ and ZA is out for voting until the 21 September.

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 22 October.

prEN IEC 61543 Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility this draft amendment is out for voting until 29 October

IEC 62873-3-3 ED2 Residual current operated circuit-breakers for household and similar use - Part 3-3: Specific requirements for devices with screw-type terminals for external untreated aluminium conductors and with aluminium screw-type terminals for use with copper or with aluminium conductors this committee draft is out for voting until 29 October.

IEC 61543 ED2 Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility this committee draft is out for vote until 29 October.
ISO/DTS 4807 Reference materials for particle size measurement - Specification of requirements has been approved.

ISO/CD 13319-2 Determination of particle size distribution — Electrical sensing zone method — Part 2: Tuneable resistive pulse sensing method has been approved.

ISO/DIS 13317-1 Determination of particle size distribution by gravitational liquid sedimentation methods — Part 1: General principles and guidelines is out for voting until 2 November

ISO/DIS 9277 Determination of the specific surface area of solids by gas adsorption — BET method (Revision of ISO 9277:2010) was approved with comments which will be considered before the draft goes to FDIS stage.

ISO/DIS 3749 Glass syringes — Determination of extractable Tungsten has been approved

ISO/DIS 18113-1 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements.

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

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

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

ISO/DIS 18113-5 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing all five parts of this standard are out for voting until 25 October.

ISO/DTS 16775, Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 although 16 members approved this draft, Germany, Switzerland and Ireland voted against, six countries abstained.

ISO 8536-3:2009/CD Amd 1 Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles — Amendment 1 was circulated for voting in August.

FINAL DRAFTS

FDIS EC 60695-2-13 ED3 89/1538 Fire hazard testing - Part 2-13: Glowing/hot-wire based test methods - Glow-wire ignition temperature (GWIT) test method for materials has been approved for publication.

FDIS IEC 60695-2-12 ED3 89/1537 Fire hazard testing - Part 2-12: Glowing/hot-wire based test methods - Glow-wire flammability index (GWFI) test method for materials has been approved.

ISO/FDIS 13322-2 (Ed 2) - Particle size analysis â Image analysis methods Part 2: Dynamic image analysis methods was out for voting in August.

FprEN IEC 61557-17:2021 Electrical safety in low voltage distribution systems up to 1000V AC and 1500V DC - Equipment for testing measuring and monitoring of protective measures - Part 17: Non AC contact voltage indicators has been approved for publication.

STANDARDS RECONFIRMED

ISO 11140-3, Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test.

ISO 11140-4, Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration (see attached Form 21)

ISO 11140-5, Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests These standards have been confirmed after systematic review.

STANDARDS APPROVED

None

STANDARDS PUBLISHED

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BS EN ISO 15883-5:2021 Washer-disinfectors Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy.

BS EN ISO 11138-8:2021 Sterilization of health care products — Biological indicators Part 8: Method for validation of a reduced incubation time for a biological indicator

BS EN ISO 20166-4:2021 Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue Part 4: In situ detection techniques

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STANDARDS WITHDRAWN
None

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