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L@b Brief Standards Newsletter – November 2021

The UK is being asked to support splitting the work on **In vitro diagnostic Next Generation Sequencing (NGS) workflows for the examination of human DNA/RNA** into 2 parts:
In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 1: Human DNA examination and Part 2: Human RNA examination.

NEW WORK ITEMS PROPOSED

BS 2646-2 Autoclaves for sterilization in laboratories: Part 2 - Guide to planning and installation.

BS 2646-3 Autoclaves for sterilization in laboratories: Part 3 - Guide to safe use, operation and maintenance.

EN 17180 Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing.

It has been proposed to adopt a project to revise the European Annex of **EN ISO 23640:2015 In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents** in an Amendment A11

NEW WORK ITEMS ACCEPTED

ISO NP 5649, Concepts and specifications for the design, development, production and use of in-house in vitro diagnostic medical devices (laboratory-developed tests)

STANDARDS TO BE REVISED OR OUT FOR REVIEW

ISO 15883-2:2006 (vers 3), Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc - Reconfirmed.

ISO 15883-2:2006 (vers 3), Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers - Reconfirmed.

ISO 15883-7:2016, Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment – Reconfirmed.

BS 2955_1993 - Glossary of terms relating to particle technology – Reconfirmed.

BS 3406-1_1986 Methods for determination of particle size distribution – Guide to powder sampling – Reconfirmed.

BS 3406-4_1993 – Methods for determination of particle size distribution – guide to microscope and image analysis methods – Reconfirmed.

BS 8471_2007 - Guide to particle sizing methods – Reconfirmed.

BS 4359_1982 – Determination of the specific surface area of powders – Recommended air permeability methods – Reconfirmed.

BS 4359-4_1995 - Determination of the specific surface area of powders -- Recommendations for methods of determination of metal surface area using gas adsorption techniques – Reconfirmed.

BS 7591-4_1993 - Porosity and pore size distribution of materials -- Method of evaluation by liquid expulsion – Reconfirmed.

BS 3625_1963 – Specification for eyepiece and screen graticules for the determination of the particle size of powders – Reconfirmed.

BS 7989_2001 – Specification for recirculatory filtration fume cupboards – Reconfirmed.

DRAFT STANDARDS

ISO/DIS 8872 Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods is out for voting until 10 February.

ISO 8362-2:2015/CD Amd 1 Injection containers and accessories — Part 2: Closures for injection vials — Amendment 1 has been approved for circulation as a DIS.

ISO 11607-1:2019/CD Amd1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1 has been approved for circulation as a DIS.

ISO 11607-2:2019/CD Amd1, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1 has been approved for circulation as a DIS.

ISO/DIS 13004 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD draft has been circulated. The UK is likely to approve.

ISO CD 20658:#### Medical laboratories – Requirements for collection and transport of samples has been circulated as a committee draft.

ISO/DIS 15189 Medical laboratories — Requirements for quality and competence has been circulated for approval by 21 December.

IEC 62974-1 ED2: Monitoring and measuring systems used for data collection, gathering and analysis - Part 1: Device requirements has been circulated as a draft for comment.

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 being circulated as a committee draft.

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 circulation as an FDIS.

EN 62606:2013 General requirements for arc fault detection devices has been circulated for approval at enquiry stage.

ISO/DIS 20804 Determination of the specific surface area of porous and particulate systems by small-angle X-ray scattering (SAXS) has been approved for circulation as a DIS.

FINAL DRAFTS

ISO 8536-3:2009/DAM 1 Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles AMENDMENT 1 has been circulated for final approval to publish.

ISO/FDIS 8536-15, Infusion equipment for medical use - Part 15 - Light-protective infusion sets for single use has been circulated for final approval to publish.

ISO/DTS 5798 Quality Practice for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by nucleic acid amplification methods has been circulated as a draft for publication.

ISO/FDIS 3749 Glass syringes — Determination of extractable tungsten is out for voting until 7 January.

FprCEN/TS 17747, Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood - DNA, RNA and proteins has been circulated for approval to publish.

STANDARDS RECONFIRMED

None

STANDARDS APPROVED

It has been decided to skip final vote and go straight to publication on the following standards

EN ISO 25424:2019/prA1 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1

prEN ISO 20776-2 - Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test - Part 2: Evaluation of performance of antimicrobial susceptibility test devices against reference broth micro-dilution

ISO/DIS 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

IEC 61558-2-14 ED2 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-14: Particular requirements and tests for variable transformers and power supply units incorporating variable transformers for general applications has been approved for circulation as an international standard.

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STANDARDS PUBLISHED

BS EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers

BS EN ISO 4307:2021 Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA

BS EN ISO 16256:2021 Clinical laboratory testing and in vitro diagnostic test systems — Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases

PD ISO/TS 22107:2021 Dispersibility of solid particles into a liquid

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STANDARDS WITHDRAWN

None

ENDS