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L@b Brief Standards Newsletter – July 2021

MedTech Europe urges the European Commission to get on with harmonisation of standards

MedTech Europe has drafted a set of recommendations: 'Considerations on the current process of harmonisation of standards under the IVD Regulation and Medical Devices Regulation' to try to expedite harmonisation of relevant standards.

The Standardisation Request for the In Vitro Diagnostic Medical Devices Regulation (IVDR) and Medical Devices Regulation (MDR) has been approved which paves the way for harmonised standards for medical devices and in vitro diagnostic medical devices to be cited in the EU Official Journal. But MedTech Europe wants to ensure that this publication is followed by a smooth and speedy process of harmonisation.

Using harmonised standards to demonstrate compliance against the general safety and performance requirements or other legal aspects is voluntary, but they are considered a key pillar of New Legislative Framework legislation, including the IVDR/MDR. MedTech Europe has highlighted the lack of harmonised standards for IVDR/MDR in many horizontal and product-specific areas which poses challenges for manufacturers, for conformity assessment, compliance with post-market requirements and when implementing significant changes to devices or quality management systems.

MedTech Europe has called on the European Commission urgently to address the following aspects of Annex III to make this possible:

• Some 'horizontal' standards (e.g., ISO 14155, 14971, etc.) cannot have 'technical' content in the same manner as a product-specific standard since they outline how to implement a process or fulfil horizontal requirements, but not how to test a product. Additional clear interpretation of Annex III should be provided urgently by the European Commission which will support the harmonisation for these so-called 'horizontal' or process standards. Given the importance of horizontal standards – as they affect ALL medical devices and should be harmonised against the IVDR/MDR as a matter of priority – a solution needs to be found to bring these standards into the European legislation.

• The terminology used in an international standard does not match 100% with that of the IVDR/MDR, since it considers many jurisdictions and often the standard originated earlier than the Regulations. Moreover, many standards define specific terms, which are urgently needed to unambiguously define its requirements, but which are not defined in the IVDR/MDR. If the HAS consultant decides that a term is a 'legally relevant term' then its definition by a standard is forbidden which will hinder harmonisation of that standard. It is asked that the European Commission either provides the standards experts with a list of 'legally relevant terms', or, preferably, clarifies that the Annexes Z should include a statement to the effect that the definitions set out in the IVDR/MDR prevail for the purpose of using the harmonised standard for the compliance to the European requirements. This will set out how specific terms should be understood for the purpose of IVDR/MDR without triggering the need to change the text of the international standard.

• Many standards reproduce requirements contained in the IVDR/MDR as this is necessary to align the European requirements to those applicable in other jurisdictions. It is vital that this continues to be the case as it enables Europe to continue exporting its rules – and therefore exporting its products – globally. The Annex III implies that no IVDR/MDR requirements can be reproduced in the text of the international standards. The European Commission should clarify that this means that the Annexes Z should not harmonise the sections of the standard where the text is the same, i.e., not more stringent. Reproducing the IVDR/MDR requirements into international standards should be celebrated and supported by the European Commission.

• Standards which normatively refer to other standards – a well acknowledged practice in standardisation – are especially at risk of not being harmonised. Surprisingly, Annex III first defines strict

requirements for such normative references before forbidding their use in the last sentence of the same paragraph. Clarification from the European Commission is needed to ensure that standards may normatively refer to other standards under the harmonisation framework, but that these specific requirements coming from normative references i.e., other standards, shall not be used to confer a presumption of conformity in the Annexes Z.

• When a standard is harmonised, the manufacturer needs time to transition to the new requirements. This implies a re-organisation of the manufacturers' processes which can take up to 3 years in the case of complex, horizontal standards. Therefore, a transition time to allow for the changes to be implemented is highly recommended. Moreover, a detailed work plan or a list in which order the standards are being prepared from the standardisation organisations will give manufacturers a better perspective on the priorities.

• The European Commission is urged to liaise with the CEN-CENELEC Management Committee on creating a public database where the information is stored in all transparency, including the reports from the HAS consultants, the status of each standard and the working plan.

• Finally, a fair mechanism should be implemented to contest the decision of HAS consultants and to promote transparency, the decisions of the HAS consultants should be made publicly available.

MedTech Europe concludes that further discussion is needed to find a pragmatic approach for the obstacles on the way to harmonisation of standards for the medical devices and IVD sectors which cover 500,000 types of products.

NEW WORK ITEMS PROPOSED

NWI Guidance for the verification of residual current monitoring devices (RCMS) in low voltage electrical installations is out for voting until 27 August.

NEW WORK ITEMS ACCEPTED

N 1144: Determination of particle concentration by small angle X-ray scattering (SAXS)

STANDARDS TO BE REVISED OR OUT FOR REVIEW

DRAFT STANDARDS

ISO/DTS 16775.2, Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2 has been approved for publication.

ISO 11607-2:2019/CD Amd1, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems – Amendment 1 is out for voting until 15 October.

ISO 11607-2:2019/CD Amd1, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes – Amendment 1 is also out to vote until 15 October.

ISO/DIS 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 devices is out for voting until 11 October.

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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 has been issued for voting at Enquiry Stage. Voting ends on 29 September.

ISO/TS 5111, Sterilization of health care products – Quality of water for sterilizers, sterilization and washer-disinfectors. A draft has been issued for comments by 24 August.

FprCEN/TS 17688-1, Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 1 - Isolated cellular RNA, Part 2 - Isolated proteins and Part 3 - Isolated genomic DNA are all out for voting until 23 September, if approved they will be published as British Standards without going through the FDIS stage.

prEN ISO 20916: In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice has been approved as a draft European Standard.

ISO/DIS 21474-2 In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 2: Validation and verification is out for voting, the UK is likely to abstain.

ISO/TC 24/SC 4 N 1140 ISO/DTS 4807 2021 Reference materials for particle size measurement — Specification of requirements this draft technical standard is out for vote until 1 August. UK is likely to abstain.

ISO 8536-3:2009/DAmd 1:2021(E) Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles has been issued for comment and voting

ISO/DIS 24166-2: Snap-on bottles for metering pumps Part 1: Tubular glass— Part 2: Moulded glass is and Part 3: Plastic are out for voting until 27 September.

ISO 26824 Particle characterization of particulate systems -- Vocabulary. A Draft for public comment has been loaded to the BSI Standards Development Portal for comment. If you have not used this system before, you will need to register here. To comment please click here.

ISO 20998-2 Measurement and characterization of particles by acoustic methods. - Part 2: Guidelines for linear theory. Is also available as a draft for public comment. You can view it and comment here.

IEC 62752 ED2; In-cable control and protection device for mode 2 charging of electric road vehicles (IC-CPD) is out for voting UK intends to make no comment.

IEC 60898-3/AMD1 ED1 Amendment 1 - Electrical accessories - Circuit-breakers for overcurrent protection for household and similar installations - Part 3: Circuit-breakers for DC operation has been approved as an IS.

ISO/DTR 24672 Nanotechnologies — Guidance on the measurement of nanoparticle number concentration has been issued as a draft for comment. Responses are required by 30 August.

ISO/DIS 14222: Space environment (natural and artificial) — Earth upper atmosphere is out for voting until 8 October.

IEC TS 63383 ED1: Cybersecurity aspects of devices used for power metering and monitoring, power quality monitoring, data collection and analysis has been issued for comment until 22 August.

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FINAL DRAFTS

ISO/FDIS 6717: In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood has been approved.

STANDARDS RECONFIRMED

None

STANDARDS APPROVED

None

STANDARDS PUBLISHED

BS EN ISO 23162:2021 Basic semen examination — Specification and test methods.

BS EN ISO 14160:2021 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.

BS EN ISO 22413:2021: Transfer sets for pharmaceutical preparations — Requirements and test methods.

STANDARDS WITHDRAWN

None

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