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Communication to Stakeholders 22 July 2020

MD008: International Organization for Standardization (ISO) standards for medical devices and protective clothing

BACKGROUND

1. To support the initiatives dealing with the impact of COVID-19, the International Organization for Standardization (ISO) has made the standards supporting biological evaluation of medical devices and protective clothing used in health care settings accessible for free.
2. The standards that have been made available include the ISO 13485 standard pertaining to quality management systems for medical devices, 19 standards supporting the biological evaluation of medical devices and three standards supporting protective clothing used in health care settings.
3. The standards are available in read-only format, and can be accessed using the following links:

- ISO 13485:2016 Medical devices — Quality management systems – Requirements for regulatory purposes
- ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risk
- ISO 10651-3:1997 Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators
- ISO 10651-4:2002 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators
- ISO 10651-5:2006 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 13688:2013 Protective clothing – General requirements
- ISO 17510:2015 Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
- ISO 18082:2014 Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases (Including ISO 18082:2014/AMD 1:2017, AMENDMENT 1)
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process

- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate
- ISO 19223:2019 Lung ventilators and related equipment — Vocabulary and semantics
- ISO 20395:2019 Biotechnology — Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR
- ISO 5356-1:2015 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
- ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- ISO 80601-2-13:2011 Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (Including: ISO 80601-2-13:2011/Amd.1:2015, AMENDMENT 1 and ISO 80601-2-13:2011/Amd.2:2018, AMENDMENT 2)
- ISO 80601-2-70:2015 Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74:2017 Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- ISO 80601-2-79:2018 Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
- ISO 80601-2-80:2018 Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
- ISO/TS 16976-8:2013 Respiratory protective devices — Human factors — Part 8: Ergonomic factors

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