Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context

Question 1: What is a medical device, active implantable medical device and an in vitro diagnostic medical device?

Medical devices are defined by Article 1 of the Medical devices directive (93/42/EEC),

Active implantable medical devices are defined by Article 1 of the Directive on active implantable medical devices (90/385/EEC),

In vitro diagnostic medical devices are defined by Article 1 of the Directive on *in vitro* diagnostic medical devices (98/79/EC),

Question 2: What are the legal requirements for placing such medical devices on the EU market and how should the compliance with them be verified and documented?

In order to place a medical device of any of the three types on the market, the manufacturer has to comply with the provisions of the applicable Directive mentioned under Q1.

Based on the level of potential hazard inherent in the type of device concerned the devices are classified in risk classes for which different types of conformity assessment procedures are applied.

For low risk devices, the manufacturer ensures and declares conformity with the applicable requirements. The Directives contain essential requirements that the device must satisfy and certain requirements on the technical documentation to be prepared by the manufacturer.

Medium and high risk devices (such as masks supplied in a sterile condition, ventilators, or diagnostic self-tests) require an intervention of a notified body which would in most cases need to assess both the manufacturer's quality management system and the specific device technical documentation prior to issuing a certification.

Notified bodies are listed in the NANDO (New Approach Notified and Designated Organisations) Information System,

Question 3: How can standards be used under the legislation?

The Directives lay down essential requirements on safety and performance of the devices they cover, but do not prescribe any specific mandatory technical solutions for the manufacturing and design of the devices. Therefore, the manufacturer can choose which technical solution to use to meet these essential requirements.

The Directives offer the possibility for manufacturers to rely on specific technical solutions, which are detailed in harmonised European standards or parts thereof. The references to these harmonised standards are published in the *Official Journal of the European Union*. Where a manufacturer chooses to follow a harmonised standard, the product is presumed to be in conformity with the applicable essential health, safety and performance requirements. The harmonised standards under the Medical devices directive most relevant for the public health crisis associated to the COVID-19 outbreak are listed in annex 1.

Most European standards for medical devices have their origin in international ISO or IEC standards. The annex 2 to this Q & A contains a table indicating the recognition of international standards under the legal systems of the member jurisdictions of the International Medical Device Regulators Forum (IMDRF).

Question 4: Where can standards be obtained?

Normally, manufacturers must purchase the standards they need from the national members of the European standardisation organisations in the field (CEN and CENELEC), i.e. the national standardisation bodies.

However, to ensure that European industry can quickly respond to the increased demand of medical devices generated by the public health crisis associated to the COVID-19 outbreak, the Commission has agreed with the European standardisation organisations that several standards are made freely and fully available by the national standardisation bodies.

Manufacturers can download these standards without cost from the online catalogues of the national standardisation bodies.

Question 5: Due to the urgency caused by the COVID-19 outbreak, is there a possibility to derogate from the normal conformity assessment procedures?

The directives prescribe that, on duly justified request, a Member State may, in the

interest of protection of health, authorize the placing on the market within the territory of the Member State concerned, of individual devices for which the conformity assessment procedures haven´t been carried out yet. The public health crisis associated to the COVID-19 outbreak is to be considered justified circumstance for that purpose.

In addition, the Commission Recommendation (EU) 2020/403 on conformity assessment and market surveillance of 13 March 2020 provides recommendations to Member States with regard to personal protective equipment and medical devices for protection (such as surgical masks, exploration gloves and some gowns). The recommendation is accompanied by a guidance document on conformity assessment procedures for protective equipment**.**

When assessing the need for a derogation, the national competent authority in a Member State may consider factors such as:

1. the degree of criticality of the use of the device for the protection of health;
2. availability of suitable substitutes;
3. documentation of compliance with a harmonised standard or other specific technical solutions ensuring fulfilment of the applicable essential requirements laid down in the relevant Directive;
4. review of reports of tests performed by competent bodies;
5. indications from vigilance and/or market surveillance.

The derogation should be temporary and the period of validity limited to what is strictly required for rendering the device compliant with the legislation or, if earlier, when suitable substitutes can be expected or the critical needs will no longer be present.

If Member States identify on the market devices for which the conformity assessment procedures have not been carried out and no valid derogation decision has been issued, they should take appropriate market surveillance measures in accordance with the relevant directive. Recent experience indicates that there is, in addition, a need to be attentive to falsified certificates and counterfeit devices.

Question 6: Is it necessary to register the devices?

In most cases there is an obligation for a manufacturer who makes devices available on the market to inform the competent authorities of the Member State in which he has his registered place of business, about the address of the registered place of business and the description of the devices concerned. Manufacturers outside the EU must have an authorised representative in the EU who then informs Member State competent authorities of the above.

Question 7: How can I get in touch with the national competent authorities?

The national competent authorities are listed here:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Question 8: Off label use of a medical device

A medical device should be used as intended by the manufacturer and described in the instructions for use. If a device is used in any other way, this is considered 'off-label' use. Off-label use of a device could entail serious risks.

When it is deemed necessary to use an existing medical device for a purpose or in a way that is different from that intended by the manufacturer, risks and benefits to the patient must be carefully assessed. The assessment may typically include steps or factors such as:

- a documented risk assessment on the use of the device
- consideration of ethical and legal implications
- implementation of suitable precautions to minimise the risk
- reviewing the risk assessment at suitable periods
- obtaining approval from the national competent authorities when required.

Question 9: Will the new Regulations on medical devices and in vitro *diagnostic medical devices replace the three current Directives?*

The new Regulations (MDR[1] and IVDR[2]) will replace the current Directives 90/385/EEC and 93/42/EEC on 26 May 2020 and 98/79/EC on 26 May 2022.

In light of the public health crisis associated to the COVID-19 outbreak and with patient health and safety as a guiding principle, Commission adopted, on 3 April, a proposal to postpone the current application date of 26 May 2020 of the Medical

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Devices Regulation (MDR) for one year is ongoing. The Commission intends to submit the proposal to the co-legislators (the European Parliament and Council) in early April 2020 with the aim to have the proposal adopted before the end of May.

Information about the new Regulations is available at
https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

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N.B. These Guidelines are intended solely for facilitating the application of Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC. However, the Commission accepts no responsibility or liability whatsoever with regard to the information in this document. This information provided in this document is:

- of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- not necessarily comprehensive and complete;
- sometimes referring to actions of external actors over which the Commission services have no direct control and for which the Commission cannot assume responsibility;
- not of professional nature or should not be read as legal advice;
- to the extent that these Q&A:s may interpret legislation, the Commission's position is without prejudice to any interpretation of this legislation that may be issued by the Court of Justice of the European Union.

Annexes:

1. Harmonised standards under 93/42/EEC - Medical devices directive with relevance to COVID-19

2. Table indicating recognition of international standards under the legal systems of the member jurisdictions of the International Medical Device Regulators Forum (IMDRF) **–** based on information provided in 2019, updated with regard to EU Harmonised standards April 2020:
https://ec.europa.eu/docsroom/documents/40606

Annex 1

Harmonised standards under 93/42/EEC – Medical Devices Directive with relevance to COVID-19

Name of harmonised standard according to 93/42/EEC - Medical Devices Directive	English title of harmonised standard according to 93/42/EEC - Medical Devices Directive
EN 14683: 2019+AC:2019	Medical face masks - Requirements and test methods
EN 455-1:2000	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
EN 455-2:2009+A2:2013	Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2006	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
EN 794-3:1998+A2:2009	Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators
EN 1282-2:2005+A1:2009	Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)
EN 1782:1998+A1:2009	Tracheal tubes and connectors
EN 12342:1998+A1:2009	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 13544-1:2007+A1:2009	Respiratory therapy equipment - Part 1: Nebulizing systems and their component
EN 13544-2:2002+A1:2009	Respiratory therapy equipment - Part 2: Tubing and connectors
EN 13544-3:2001+A1:2009	Respiratory therapy equipment - Part 3: Air entrainment devices
EN ISO 5359:2008	Low-pressure hose assemblies for use with medical gases (ISO 5359:2008) EN ISO 5359:2008/A1:2011

EN ISO 5366-1:2009	Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)
EN ISO 7376:2009	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009)
EN ISO 7396-2:2007	Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)
EN ISO 8185:2009	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)
EN ISO 9170-2:2008	Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)
EN ISO 9360-1:2009	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)
EN ISO 9360-2:2009	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)
EN ISO 10079-1:2009	Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)
EN ISO 10079-2:2009	Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:1999)
EN ISO 10524-1:2006	Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524- 1:2006)
EN ISO 10524-2:2006	Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)
EN ISO 10524-3:2006	Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)
EN ISO 10524-4:2008	Pressure regulators for use with medical gases - Part 4: Low-pressure regulators (ISO 10524- 4:2008)
EN ISO 10651-2:2009	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651- 2:2004)
EN ISO 10651-4:2009	Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)

EN ISO 10651-6:2009	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
EN ISO 13408-1:2015	Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
EN 13795-1: 2019	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
EN 13795-2:2019	Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15001:2011	Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)
EN ISO 15002:2008	Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)
EN ISO 17510-1:2009	Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)
EN ISO 17510-2: 2009	Sleep apnoea breathing therapy – Part 2 - Masks and application accessories
EN ISO 18777:2009	Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005)
EN ISO 18779:2005	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements (ISO 18779:2005)
EN ISO 21969:2009	High-pressure flexible connections for use with medical gas systems (ISO 21969:2009)
EN ISO 23328-1:2008	Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328- 1:2003)
EN ISO 23328-2:2009	Breathing system filters for anaesthetic and respiratory

	use - Part 2: Non-filtration aspects (ISO 23328-2:2002)
EN ISO 23747: 2009	Anaesthetic and respiratory equipment -- Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
EN ISO 26782: 2009	Anaesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans
EN 60601-1: 2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000)
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
EN 60601-1-4:1996	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996) EN 60601-1-4:1996/A1:1999 (IEC 60601-1-4:1996/A1:1999)
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 60601-1-8:2007	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006) EN 60601-1-8:2007/AC:2010 EN 60601-1-8:2007/A11:2017
EN 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard:

	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010)
EN 60601-2-4:2003	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601- 2-4:2002)
EN 60601-2-12:2006	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001)
EN 60601-2-17:2004	Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment (IEC 60601-2-17:2004)
EN 60601-2-24:1998	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)
EN 60601-2-52:2010	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009) EN 60601-2-52:2010/AC:2011
EN 62304:2006	Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008
EN 62366:2008	Application of usability engineering to medical devices
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)