Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19

Q1: Is there any applicable EU legal frameworks in the case of 3D printing?

3D Printing (3DP) – also known as Additive Manufacturing (AM) - is a manufacturing process that uses 3D Printers – also known as Additive Manufacturing machinery - to fabricate other market products.

3D Printers – also known as Additive Manufacturing machinery are means of production that can be used to manufacture various products for different applications.

3D printers are among the so-called 'harmonised products' for which there is specific EU product harmonisation legislation in place. In particular, they fall under the definition of machinery under the Machinery Directive 2006/42/EC. Thus, manufacturers must ensure the compliance of 3D Printers with the applicable essential health and safety requirements of the Machinery Directive, compose a technical file and affix the CE-marking before placing them on the EU internal market.

Besides the Machinery Directive, other EU pieces of legislation may apply to 3D printers; i.e. the Electromagnetic Compatibility Directive 2014/30/EC, and EU legislation on chemicals, WEEE 2012/19/EU, RoHS II 2011/65/EU Directive and Directive (EU) 2017/2102, and REACH 1907/2006/EU.

Products designed and manufactured in accordance with the Machinery Directive 2006/42/EC can circulate freely throughout the internal market and Member States may not introduce additional and/or diverging requirements regarding the manufacturing and placement on the market of such products.

3D printed products in themselves may be used to produce medical devices which fall within the scope of specific EU product legislation, such as the Medical Devices Directive 93/42/EEC[1]. Therefore, manufacturers of such medical devices must ensure that 3D printed products meet the requirements of the applicable EU legislation[2], carry out the necessary conformity assessment procedures, compose a technical file, draft the EU declaration of conformity and affix the CE marking, before placing them on the EU market[3]. (cf. questions below)

[1] Please note that when the new Regulation (EU) 2017/745 enters into full application, it will replace the Directive 93/42/EEC. However, according to the transitional provisions of Art. 120 of that Regulation, devices compliant with Directive can continue to be placed on the market under certain conditions and in accordance with certain timelines.

[2] Currently, medical devices are ruled by Directive 93/42/EEC, concerning medical devices; Directive 98/79/EC on in vitro diagnostic medical devices and Directive 90/385/EEC relating to active implantable medical devices.

[3] For more information on the product coverage of EU product legislation and the CE marking, see: https://ec.europa.eu/growth/single-market/ce-marking/

Q2: Are there any mandatory EU standards for 3D printers?

Concerning the 3D printer, the manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of such risk assessment.

The Machinery Directive 2006/42/EC lays down essential requirements on health, safety and performance of the products they cover. However, this EU legal framework is technologically neutral and does not prescribe any specific mandatory technical solutions for the design of the products. Therefore, a number of technical solutions may be used by manufacturers to meet these essential requirements.

The Machinery Directive offers the possibility for manufacturers to rely on specific technical solutions, which are detailed in **harmonised European standards** or parts thereof the references of which have been published in the *Official Journal of the European Union (OJEU)*. Should a manufacturer choose to adopt such a technical solution, the product is presumed to be in conformity with the applicable essential health, safety and performance requirements that the harmonised standard aim to cover. Otherwise, if the manufacturer choose to adopt any other technical solution, (s)he must give a detailed explanation on the compliance of such technical solution with the EU legislation requirements in the technical file.

The following are some of the most relevant **harmonised standards** cited in the *OJEU* under the Machinery Directive[4] for laser-based 3D printers (metal):

- EN ISO 12100 (Safety of machinery – General principles for design – Risk assessment and risk reduction)
- EN 60204-1 (Safety of machinery – Electrical equipment of machines)
- EN 13849-1 (Safety of machinery – Safety-related parts of control systems)
- EN 13850 (Safety of machinery – Emergency stop function – Principles for design)
- EN ISO 11553-1 (Laser processing machines)
- EN 1127-1 (Explosive atmospheres – Explosion prevention and protection)
- EN ISO 19353 (Safety of machinery – Fire prevention and fire protection)

For plastic printers, fire and explosion standards are relevant too.

In addition, it is useful to consider some **non-harmonised** standards for laser products/safety;

- EN 60825-1 (Safety of laser products – Part 1: Equipment classification and requirements)
- EN 60825-4 (Safety of laser products – Part 4: Laser guards)

Q3: Is there any applicable EU legal framework for 3D printed products used in a medical context?

Depending on the intended purpose of the 3D printed product, they may qualify as medical devices, or accessories according to the definitions set out in the medical devices legislation. Such products

[4] Harmonised standards for machinery: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery

must fulfil all applicable requirements of Directive 93/42/EEC[5]. In particular, accessories of medical devices (which are not in themselves medical devices), but are intended by the manufacturer to be used specifically to enable the use of a medical device, may qualify as devices and shall meet the requirements of the medical devices legislation. This is not necessarily the case for parts and components of medical devices, which don't have regulatory status under the Medical Devices Directive 93/42/EEC, however are nonetheless expected to satisfy the safety requirements of a medical device, being part thereof.

For example, 3D printed plastic valves used in respiratory ventilators may qualify as either accessories of medical devices or their parts and components.

Where the conformity assessment procedure for the medical device is based on the Manufacturers' Quality Management System, the following harmonized standard may be used:

- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018

According to such standard, the manufacturer should validate the production process as set out in section 7.5.6 EN ISO 13485:2016. Among other requirements, the validation procedure should also include the equipment qualification.

Harmonised standards on additively manufactured parts to be used in the medical devices sector.

- There are no harmonised standards that specifically apply to additively manufactured parts to be used in the medical devices sector. However, other standards may be used.[6]
- Existing safety standards related to the manufacturing and use of the specific part/component in the medical devices sector are applicable regardless of the type of machine/process used for their production.
- It is important to choose the correct materials to develop the needed parts or components (e.g. in the case of ventilator valves, compatibility testing between the material and the enriched oxygen fluid to be administered, should be performed)
- It is important to apply appropriate post-processes (e.g. cleaning, sterilisation, biological evaluation) to the manufactured part to ensure the absence of loose powder particles and any other potentially harming elements.
- Other specific requirements laid down in the EU legislation on medical devices are addressed by standards, such as standards on the information to be supplied by the manufacturer, on medical electrical equipment, etc.

Other than harmonised standards, design specifications for specific devices and device parts, components or accessories can be acquired either through an agreement with an existing medical device manufacturer or though contacting a national competent authority.[7]

[5] Directive 93/42/EEC. See also footnote 1, regarding the new Regulation (EU) 2017/745.
[6] See ISO ISO/ASTM 52901:2017 [ASTM F 42] https://www.iso.org/standard/67288.html
[7] Contact information can be found on the medical devices sectorial website of the European Commission.

List of a recently published list of harmonised standards under the Medical Devices Directive relevant for ventilator parts, components and accessories

- 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 (ISO 17510-2:2007)
- EN 12342:1998+A1:2009 Breathing tubes intended for use with anaesthetic apparatus and ventilators
  EN ISO 8835-3:2009 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007) EN ISO 8835-3:2009/A1:201
- 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 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

Issues related to the material used
It is essential that the material used for 3D printing are safe and performant and are tested for the purpose of the 3D printed product and its final use. e.g. Thermal Resistance, Mechanical Resistance, Chemical resistance, Resistance to Sterilization.

Q4: Are there any design specifications available to produce 3D printed products used in ventilators?

- In order for 3D printing companies to manufacture parts, components or accessories of medical devices, they should get into contact with an existing medical devices manufacturer and request the design specification required. These specifications will lay out the technical designs and requirements for the product. For example, to manufacture ventilator valves, it would be crucial to have access to the file of the design in order to know the dimensional characteristic, material to use and tolerances required.

- It should also be noted that every time a new product is intended to be 3D printed, the qualification of the concerned printing process should be updated. This is necessary to confirm that as a result of using the printer, the correct geometry of the 3D printed product is achieved. In addition, the process parameters for the subsequent mass production of such 3D products should be identified and confirmed.

Q5: Can a 3D printed product falling within the scope of the Medical Devices Directive be placed on the market by virtue of a declaration of conformity?

As above in Q3, this depends on whether or not the product in question can be qualified as a medical device. Where the product qualifies as a medical device, and is a low-risk device (e.g. Class I), then it can be placed on the market through a declaration of conformity issued either by the manufacturer or the authorised representative.