

Guidelines for in-house fabrication of respiratory devices accessories using 3D printing

Introduction

With the Covid-19 crisis, availability of medical devices has been put under pressure at hospital and national level. In this context the FAMHP published a circular¹ broadening the scope of hospital in-house manufacturing for medical devices that are not available in due time to treat a patient. The circular authorizes hospitals to subcontract the manufacturing of these medical devices to third-party organizations. The role of healthcare providers and health institutions is essential to allow a rational deployment and a continuous assessment of these crisis solutions when the situation requires it.

Many companies, universities, fablabs, and citizens have been helping in manufacturing some of these missing items for the past few weeks. Even if the FAMHP understands that a crisis situation can lead to a temporary redefinition of the benefit/risk ratio insofar as the absence of usual means becomes the comparator (and no longer the original product that has become inaccessible), it is necessary to build on the existing regulatory framework, as a guide which must make it possible to ensure patient safety when using these products.

This guidance gives a framework for the 3D printing production. The criteria stated in the circular must be met.

You can send your questions or comments about this document to coronashortages@fagg-afmps.be with the following subject: comments/questions related to Belgian national guidance on 3D printing.

Framework and guidance²

3D Printing(3DP) –also known as Additive Manufacturing (AM) -is a manufacturing process that uses 3D Printers to fabricate other market products. 3D printing is a new technology which, unlike conventional manufacturing processes, proceeds by depositing successive layers of material until three-dimensional objects are obtained. This manufacturing process, which also includes the digital design of the objects to be manufactured, is based on several families of manufacturing processes allowing fine adaptations of the manufactured objects, both in terms of shapes as of materials, functionalities or even mechanical properties.

3D printers are among the so-called 'harmonized products' for which there is specific EU product harmonization legislation in place. In particular, they fall under the definition of machinery under the Machinery Directive 2006/42/EC.

3D printed products in themselves may be or 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.

EU standard for 3D printing

In annex you will find :

- the EU standards applicable for 3D printers
- the EU standards applicable for 3D printed products used in a medical context
- the harmonized standards under the Medical Device Directive relevant for ventilator parts

¹ [Circular for care institutions on the \(outsourcing of the\) manufacture and reprocessing of medical devices and their accessories](#)

² <https://ec.europa.eu/docsroom/documents/40562>

- the harmonized standards related to biocompatibility of materials

Recommendation relevant for ventilator parts, components and accessories

As ventilator parts, its components and accessories are in direct contact with the airflow of the patient for rather long periods of time (circa 5 to 7 days), the technical committee³ “Emergency Production of medical devices” **provides below an overview of the risks that can be linked with an undocumented use of 3D printing technologies** applied to these components and accessories . This document should **help hospitals and subcontractors to limit these risks**.

It is thus crucial that the hospital and its subcontractor for such critical parts perform a risk analysis. The FAMHP recommends all hospitals to contract with an organization having extensive knowledge of the ISO14971 (Application of risk management to medical devices) and ISO13485 (Medical devices — Quality management systems) standards and capable of designing and manufacturing according to these standards. These organizations⁴ will be able to support hospitals in their pursuit of **maximum safety for patients and medical staff**.

If, for any reason, a hospital chooses to contract with a not ISO13485 compliant organization, the FAMHP recommends the hospital and its subcontractor to take into account the following risks when proceeding with the risk analysis. We also ask all organizations currently printing these connector parts to proceed to this minimal risk analysis and if they cannot ensure maximal safety, to redirect hospitals towards organizations that can.

Main risks associated with the use of respiratory devices and accessories

1. 3D printed parts do not have the same properties as their injection molded counterparts. This means that an exact 3D printed copy of a connector will not per se have the same properties as an original one. **One must avoid that components fail (e.g. break, leak, bend or clog), which could lead to a discontinuity of the airflow or bring medical staff in contact with pathogens.** This means mechanical performance of 3D printed elements must be tested.
2. All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimize risk of contamination of the patient’s airway. **One must avoid that biologically contaminated components would be used that could bring patients in contact with pathogens.** This means that 3D printing should happen according to good practices, and that methods of decontamination/ sterilization must be taken into account.
3. The properties and behaviors of most 3D printing materials are not known when used in gas pathway of respiratory devices. **One must avoid the use of materials that could release particles/chemical agents or undergo physical/chemical reactions with gas creation that could end up in the patients’ respiratory system.** This means a risk analysis must be performed based on standards and known material properties in different environments.

Recommendations to take into account throughout design, manufacturing, testing, and procurement

1. A **full functional analysis** should be made by both the hospital and the manufacturer, including:
 - o Medical purpose(s) and performances,
 - o Required mechanical strength,
 - o Duration of use,
 - o Direct contact with patient? With breathing gases?
 - o Should be transparent/translucent?
2. **Design adaptation** should take into account:

³ Experts:

- *Benoît Herman, UCLouvain, senior researcher in design of medical devices, head of CREDEM technology platform*
- *Kyun Thibaut, Covartim, founder and managing director*
- *Jos Vander Sloten, KULeuven, Full professor, Biomechanics section, Mechanical Engineering Department, Fellow – EAMBES and IAMBE*

⁴ An updated list of these organizations can be found on the website of the FAMHP.

- Mechanical strength of selected material and process⁵,
 - Usual shape alterations due to manufacturing process (and post-processing),
 - Required tolerances (most parts are tight-fitted with tubes).
3. **Materials selection** must be done taking into account at minimum the following requirements:
- Must be cleanable chemically with a mandatory “validation/documentation” certifying that no residue of chemicals will remain in/on the device, or cleaned without chemicals and sterilizable (autoclave),
 - Must be biocompatible according to ISO 10993
 - Should be, as much as possible, compliant to ISO 18562-1:2017⁶
 - i. The chosen material must be reasonably pure and simple in nature (minimize the use of additives where possible).
 - ii. For components requiring flexibility, avoid the use of materials requiring plasticizers. Good candidates are those materials that belong to the polyolefin family, examples include polyethylene (PE, including PET) and polypropylene (PP).
 - iii. For structural components, materials such as polycarbonate (PC), acrylonitrile butadiene styrene (ABS), or polyamide (PA) should be used. It should be stressed that some of these thermoplastic materials are available under a medical grade (ISO 10993.1) and should therefore be preferred to avoid any variability from batch to batch and any contamination. Some photopolymerizable resins (e.g. used for dental applications) could also be used, but the resulting parts might be more brittle.
 - iv. Polyvinyl chloride (PVC) must be avoided in the patient gas pathway.
4. Manufacturing process should occur in a sufficiently **clean** environment.
5. Manufacturing should also include proper means of **quality control for the finished product**.
6. **Biocompatibility** must be ensured throughout the entire manufacturing process, or must be guaranteed at the end of it. Validation should include an analysis of the amount of particles released according to experimental conditions adopted in clinic, thus air flow and pressure.
7. **Results of testing** must be made available for consultation by the hospital and the FAMHP.
8. **Traceability:**
- Traceability document should be provided for each step from needs and functional analysis to delivery.
 - Remaining risks should be identified and clearly communicated to the hospital.
9. All 3D printed parts coming into contact with the patient’s breath must be **disposable** or designed to be reusable.

⁵ Classical mechanical tests (compression or traction) should be completed by a leakage test under pressure of the atmosphere to be used (even excessive if this situation can occur in practice in hospital). Keeping in mind the specificity of 3D printing technologies with a higher risk of variability (production point by point), this test should be realized on each sample over a period of at least one min with comparison to similar device approved on the market). This assessment should be performed after first cycle of sterilization. If submitted to a recycling process, this test should be repeated.

⁶ [Rapidly Manufactured Ventilator System, RMVS001 MHRA](#)

EU standards for 3D printers :

The following are some of the most relevant **harmonized standards** cited in the *OJEU* under the Machinery Directive⁵ 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-harmonized** 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)

EU standard for 3D printed products used in a medical context

- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

Harmonized standards under the Medical Device 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

Harmonized standards related to biocompatibility of materials

- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Test for systemic toxicity
- ISO 10993-13:2010 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-17:2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances