Ultimaker

Ultimaker HQ
Stationsplein 32
3511 ED Utrecht
The Netherlands

info@ultimaker.com
ultimaker.com
+31 883 83 40 00

Guidance on 3D printing and design support for COVID-19

Date: Thursday, April 9, 2020

Think before you print

Times are changing quickly. And as initiatives progress, it becomes clear that there are still many questions and ambiguities around what to do and (maybe even more importantly) what **not** to do.

Please note: Because of all the rapid changes and advancing insights, additional guidance may need to be considered.

Some useful starting points:

- First: Do no harm!
    - Medical applications and personal protective equipment (PPE) require many safety measures for good reasons
        - The European Commission provided legal context for producing medical parts and addressing safety when using 3D printing. See: https://ec.europa.eu/docsroom/documents/40562
        - See appendix 1 for a non-exhaustive list of relevant (EU) regulations and standards
    - Other applications (non-medical, non-PPE) may be regulated less severely, they still need to be safe to use.
- Ultimaker is a manufacturer of printers, not of medical equipment or products
    - We should let medical professionals decide what's needed and what's useful
    - We may be able to support those professionals with help on design, but it should be their call!
    - We should only produce parts if requested to do so by medical professionals and under their responsibility
    - Please consider that for some parts you may be deriving from OEM parts Intellectual Property rights may be an issue, even in these times of crisis. This needs to be considered and determined prior to designing and printing
- 3D printing may not be the best option for what is needed
    - Even if it is possible to print something, it doesn't mean it should be printed
    - Other technologies may be more suitable, especially when large numbers are concerned!

- A disclaimer is needed in all cases! This must emphasize:
    - Intended use, user, and use environment
    - Limitations and boundaries for use
    - Who is responsible for use and testing before use

Enthusiasm to help is great. But we must not forget that any 3D design or product offered should meet some basic requirements. This guidance focuses on medical and related applications, which includes but is not limited to:

- Personal protective equipment (PPE)
- Spare parts for medical equipment
- Add-ons for medical equipment and PPE, like splitters, adapter pieces, etc.

3 basic requirements for 3D printed medical and related products

1. Is there a **need** for the design or product, which is supported by a request?

This requirement is met if:

- An original or equivalent certified product is not available to the end-user (healthcare center, doctor, hospital, producer of medical equipment)
- The end-user or their representative has requested (support in making) an alternative product to fill a temporary gap in supply
- The end-user takes responsibility for using the product based on requirements 2 and 3

2. Is the solution offered **safe** for its end-user?

This requirement is best met if support is limited to design support for healthcare professionals like doctors and producers of medical equipment! Failure to meet this requirement can lead to liability issues – both legally and ethically.

For the resulting product, the following applies:

- Essential health and safety requirements must be met
- Healthcare professionals and end-users should confirm this based on a risk assessment. This risk assessment must take into account:
    - Suitability for intended use, user, and use environment based on a list of requirements
    - Impact of materials used
        - Cleanability (need for sterilization, disinfection?)
            - Disinfection: e.g. 70% alcohol solution

        - Sterilization e.g. steam (121 to 134 °C), Ethylene oxide, Electron Beam
      - Risk of irritation or sensitization (e.g. contact dermatitis)
    - Comfort during use
    - Mechanical hazards like:
      - Wear and tear
      - Cutting
      - Breaking
    - Production environment. Where possible this should be a certified facility capable of ensuring:
      - Consistency
      - Hygiene including avoiding contamination with allergens of chemical, animal, or other nature
      - Providing production data (date, location, design, printer, material plus batch)
- Applicable rules from regulations and standards are met
    - Confirmed by relevant experts which can be e.g. certification institutes, medical institutes or OEMs
    - TÜV SÜD has created free guidance documents (e.g. checklists) and other services (e.g. technical report) on using Additive Manufacturing technologies for printing parts and products relevant during the current COVID-19 pandemic and the breaking-off of supply chains. For more information contact them directly via am@tuev-sued.de
    - See appendix for other country-specific links

Please note that regulations and international standards apply to personal protective equipment (PPE), like face masks, filters, goggles, some face shields, as well as to medical devices and (spare) parts. See appendix 1 for a non-exhaustive overview of relevant regulations, standards, and links.

3. Does the design or product offer the **best solution**?

This requirement is met if:

- The design or product is fit for purpose
    - Based on the request from the end-user make sure the intended use is clear
    - Can the product be used as intended or even as claimed?
    - For medical applications this needs to be confirmed by the end-user
    - Even then disclaimers are needed to emphasize do's and don'ts
- No better alternative available
    - Especially in case of PPE and medical devices, healthcare centers etc. are required to use:
      - Original certified products when available

        - The next best thing if original certified products are not available and…
        - That next best thing is considered safe enough by the end-user
    - ‘Better alternative’ is to be decided by the end-user and can relate to:
        - Functionality
        - Production and/or delivery time (in case of equal functionality)
        - Cost price (in case of equal functionality and similar time to availability)
    - 3D printing is often not the best alternative

Are there any exemptions to normal rules and regulations?

In the Netherlands, the RIVM recognizes that in case of shortages of medical supplies some flexibility is needed, as do similar institutions in other countries, like the FDA in the US. However, there are a couple of boundary conditions to allowing alternative products that have not undergone the normal product approval procedure and that do not carry a CE mark or the likes of it.

Please note: Boundary conditions may vary per country.

In the Netherlands, boundary conditions apply if:

1. There is no approved and certified alternative available
2. An explicit request is made by the healthcare institution in question
3. The healthcare institution takes full responsibility for the use of the alternative product

In order to make all three happen: Involve healthcare professionals as early as possible.

For the Netherlands you can find more info with the ‘Inspectie Gezondheidszorg en Jeugd’:
https://www.igj.nl/onderwerpen/coronavirus/nieuws/2020/03/23/coronavirus-meer-ruimte-voor-fabrikanten-en-leveranciers-bij-tekort-aan-medische-hulpmiddelen

What about non-medical applications?

Just make sure the application is:

- Useful
- Safe to use
    - Common sense/ basic risk assessment. (See requirement 2: Is the solution safe?)
    - General Product Safety Directive applies

- Helping to prevent the virus from spreading further

Avoid stating suitability for medical/healthcare applications. Or even better: Explicitly state it is not intended for that!

Appendix 1: Non-exhaustive overview of relevant regulations and links

1. Potentially relevant (EU) standards, regulations, and guidelines

Medical specific

- REGULATION (EU) 2017/745 (MDR)
  - Note: date of entry into force may be delayed
  - see: https://ec.europa.eu/health/sites/health/files/docs/20200325_news_md_en.pdf
  - Council Directive 93/42/EEC concerning medical devices would then still apply
- REGULATION (EU) 2016/425 (PPE-Regulation)
- EN 149:2001 + A1:2009: Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking (commonly referred to as 'FFP masks')
- EN 14683:2019: Medical face masks - Requirements and test methods
- EN 166:2001: Personal eye-protection – Specifications
- EN 14126:2003 + AC 2004: Protective clothing – Performance requirements and tests methods for protective clothing against infective agents
- EN 14605:2009 + A1:2009: Protective clothing against liquid chemicals – performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only
- EN 13795-1:2019: Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns
- EN 13795-2:2019: Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – Part 2: Test methods

Additive manufacturing specific:

- DIN SPEC 17071: Additive manufacturing — Requirements for quality-assured processes at additive manufacturing centers.
- ISO/ASTM 52904: Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications

2. Other useful links

EU:

- Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19: https://ec.europa.eu/docsroom/documents/40562
- EU Standards freely available: https://ec.europa.eu/commission/presscorner/detail/en/IP_20_502
- EU Commission Q&A: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_558
- https://3dprintmagazine.eu/europese-commissie-schept-duidelijkheid-in-regels-rond-3d-printen-medische-producten/
- Postponement the Medical Device Regulation? https://ec.europa.eu/health/sites/health/files/docs/20200325_news_md_en.pdf

US:

- FDA. Enforcement Policy for Face Masks: https://www.fda.gov/media/136449/download
- Strategies to Optimize the Supply of PPE and Equipment: https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe-index.html
- Medical devices and the COVID-19: https://www.fda.gov/medical-devices

NL:

- Inspectie Gezondheidszorg en Jeugd: https://www.igj.nl/onderwerpen/coronavirus/nieuws/2020/03/23/coronavirus-meer-ruimte-voor-fabrikanten-en-leveranciers-bij-tekort-aan-medische-hulpmiddelen
- https://3dprintmagazine.eu/europese-commissie-schept-duidelijkheid-in-regels-rond-3d-printen-medische-producten/