Quality gate for medical AM parts urgent production for COVID-19

Disclaimer:

I. TÜV SÜD is taking part in the National Additive Manufacturing Innovation Cluster (NAMIC) initiative as an independent third party that is providing testing services to verify / confirm quality and consistency for industrial AM production according to pre-defined test requirements and schemes.
II. None of the tests and assessments performed constitute a certification of medical devices.
III. All scope of work is subjected to the approval of Health Science Authority (HSA) of Singapore. TÜV SÜD does not act on behalf of HSA.
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Template to issue technical reports on prototypes of 3D printing products due to the breaking supply chains for COVID-19

This document is intended to serve as a basic information gathering tool in the current situation of the corona pandemic. All the elements in this list can be either found in the named standards or in the training courses of TÜV SÜD. TÜV SÜD assumes no liability.

The issued technical report can only be used for internal publication. If the company want to use this report as a marketing tool, a written consent from TÜV SÜD is necessary.

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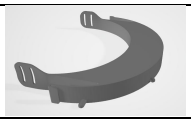
1. Elements of AM workflow and crucial KPIs

1.1. General information

Required information for technical report	**Example statements/info (depending on technology and part the example can apply)**	**Information from Manufacturer** To be filled by manufacturer or relevant documents need to be attached
Part picture		
Product designation (envisioned use or intended purpose)	3D printable face shield which can be used to shield of the facial zone against liquids for medical personal.	
Check of material / material properties		
Material used	PLA (optional CPE)	
Material certified for medical application? (Y/N plus type of certification)	No	
Material can be sterilized? (Y/N plus methods)	No, needs to be disposed after use, single time usage	
Print settings (range)	Speed, Nozzle, Temperature, layer hight etc.	
Further recommendations	Use of PPE	
Regulation / Standards that apply	REGULATION (EU) 2016/425 EN 166 EN 168	
Design Check / Compatibility with inhouse AM technology	This part can be printed with any plastic AM technology, (**digital part attached** e.g. 3D-Modell or STL)	

1.2. Quality assurance

Trained and/or skilled personnel	AM machine operator is trained by machine provider (**Certificate attached**) AM Quality Expert trained by Institution XYZ	
Clear structured documents for traceability		
- Process descriptions and work instructions	Description of all required steps for the production and all related work instructions/ PPE (Masks?) exist (**see attached**)	
- Checklists	What does the machine operator have to check in order to follow the process correctly? Manufacturer should prepare a checklist (**see attached**)	
Functional infrastructure		
- Qualified systems and processes	Are the used systems/processes qualified to produce parts with these requirements? Installation and Operational Qualification (IQ and OQ) of Systems and processes	
- Production environment and mediums	Atmosphere conditions etc.	

1.3. Data preparation (parameter settings)

Specification of the following process steps and their testing documentation		
- Part placement and support on build plate	Orientation and support fixed, but placement on build plate changeable	
- Slice data generation	Definition of layer height provided, Defined parameter set, etc.	
- Archiving data (3D-file, parameters, etc.)	Define data process for basic traceability	

1.4. Feedstock management

Material selection, storage and management	Selection via “Material catalogue” Charge control Storage environment	

1.5. System-related pre-processing

System preparation:		
- Preparatory steps (indicated by the manufacturer) for the restoration of the initial machine state for the start of the following production run with checklist or Work instruction	e.g. inspection of system, cleaning of chamber, refilling of feedstock	
Setup for production run:		
- Feedstock state in the machine	State (Humidity, Damage, Temperature etc.)	
- Sufficient feedstock and support material (filament)	Defined amount of material needed for the specific parts/builds	

1.6. Process guidance

System operation		
- Observing the indicated operating steps by the manufacturer	Checklist/tutorial provided by machine provider	
- Logging/documenting the production with as much data as possible (e.g. process parameters, number of layers)	e.g. process parameters, number of layers	

1.7. System related post-processing

- Part removal	Following the WI for part removal (**see attached**)	
- System clean-up	Following the WI for cleaning the machine, preparing for next job (**see attached**)	
- Single part handling, if necessary (e.g. separation of build plate, support removal)	e.g. separation of build plate, de-powdering, support removal	

1.8. Part specific post-processing

Depending on industry and application, different part-specific post-processing techniques are necessary. For the example of medical application this can include:		
- Cleaning of the part to remove all residual powder or process residues	Cleaning of the part to remove all residual powder or process residues	
- Packaging depending on the use-case	Simply packaging sufficient	
More to be filled out by Manufacturer		

2. Risk assessment by Manufacturer

Risk management for AM: The following table needs to be filled with the most important risks for the intended use and how to reduce or minimize them. The first few rows are only examples and can or cannot apply, depending on use case, technology and user.

Failure	**Harm/risk**	**Root cause**	**Risk control**
Wrong handling of feedstock	Contamination or degradation of material	Wrong storing conditions	Clear definitions for storing conditions
Wrong preparation of the AM-System (wrong feedstock	Defective part or unusable part	No feedstock check before process or untrained personnel	Update Work instruction /Checklist with steps and/or train personnel
Wrong process parameters	Defective part	No fixed parameter set or untrained personnel	Fix parameters and/or train personnel
More to be filled out by Manufacturer			

3. Providing sample of 3D printed part

Sample part must be sent to TÜV SÜD Additive Manufacturing Center Singapore for assessment of design and production capabilities.

Address: TÜV SÜD PSB, 1 Science Park Drive, S118221

Email contact: keshia.kon@tuv-sud-psb.sg

4. Next steps necessary for PPE (non-exhaustive list) for export to EU market

Further steps for PPE can be the following:

Apply Regulation (EU) 2016/425 including but not limited to:

- Classify risk category after Annex I
- Comply to the applicable “Essential Health and Safety Requirements” of Annex II
  - 1.2.1.1. Suitable constituent materials
  - 1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user
  - 2.3. PPE for the face, eyes and respiratory system
  - Possible standards for testing this are EN 166 or EN 168
- Preparing of the Technical Documentation (Annex III of PPE-Regulation)

- Internal production control (Module A) of Annex IV
- CE-self declaration of conformity structured after Annex IX

Depending on risk category and intended use, different, less or more steps can be necessary.

5. Evaluation of PPE for Emergency Usage in Singapore subjected to Health Science Authority (HSA) approval

*Partial Test Requirements against EN166 :2001 Personal Eye Protection	Tests Scope
Refer to disclaimer	
6 Design & Manufacturing Requirements	
6.1 General Construction **6.1 General construction** Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomf injury during use.	applicable
6.2 Material **6.2 Materials** No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation.	applicable
6.3 Headband **6.3 Headbands** Headbands, when used as the principal means of retention, shall be at least 10 mm wide over any portion which may come into contact with the wearer's head. Headbands shall be adjustable or self-adjusting.	applicable
Clause 7 basic requirements	
7.1.1 Field of vision	Applicable but not related to 3DP. TUV SUD cannot assess this.
7.1.2 Optical requirements	Applicable but not related to 3DP. TUV SUD cannot assess this.
7.1.3 Quality of material and surface Except for a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation. The assessment shall be carried out in accordance with the method specified in clause 5 of EN 167:2001.	Applicable but not related to 3DP. TUV SUD can assess.
7.1.4 Robustness	
7.1.4.1 Minimum Robustness	Not applicable for oculars without light filtering effects

<table>
<tr><td>7.1.4.2 Increased robustness</td><td></td></tr>
<tr><td>7.1.4.2.1 Unmounted oculars</td><td>N/A</td></tr>
<tr><td>7.1.4.2.1 complete eye protectors and frames
7.1.4.2.2 Complete eye-protectors and frames

The complete eye-protector or frame shall withstand the lateral and frontal impacts of a steel ball striking at a specified speed.

The diameter of the steel ball and the corresponding impact speed are given in Table 5.

Table 5 — Requirements relating to increased robustness of complete eye-protectors
<table><tr><td rowspan="2">Size, mass and speed of steel ball</td><td colspan="2">Spectacles</td><td colspan="2">Goggles</td><td>Face-shields</td></tr><tr><td>Frontal impact</td><td>Lateral impact</td><td>Frontal impact</td><td>Lateral impact</td><td></td></tr><tr><td>22 mm nominal diameter steel ball, of 43 g minimum mass, at a speed of approximately 5,1 m/s</td><td>√</td><td>√</td><td>√</td><td>√</td><td>√</td></tr></table>
The test shall be in accordance with the method specified in 3.2 of EN 168:2001.
c) ocular housing or frame fracture : an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame;</td><td>Applicable. Propose to test without head form or replace with a mechanical strength test on 3DP part</td></tr>
<tr><td>7.1.5 Resistance to ageing</td><td>NA</td></tr>
<tr><td>7.1.5.1 Stability at an elevated temperature (clause 5 of EN 168:2001)</td><td>NA</td></tr>
<tr><td>7.1.5.2 Resistance to UV (oculars only)</td><td>NA</td></tr>
<tr><td>7.1.6 Resistance to corrosion (metal part only)</td><td>NA</td></tr>
<tr><td>7.1.7 Resistance to ignition</td><td>NA</td></tr>
<tr><td>7.2 requirements</td><td></td></tr>
<tr><td>7.2.1 Protection against optical radiation</td><td>NA</td></tr>
<tr><td>7.2.2 Protection against high speed particles</td><td>NA</td></tr>
<tr><td>7.2.3 Protection against molten metals and hot solids</td><td>NA</td></tr>
<tr><td>7.2.4 Protection against droplets and splashes of liquids (12.2 of EN 168:2001)
7.2.4 Protection against droplets and splashes of liquids

Eye-protectors for use against droplets (goggles) and splashes of liquids (face-shields) shall be tested in accordance with the methods specified in clause 12 of EN 168:2001. The results shall be considered to be satisfactory if:

a) no pink or crimson colouration appears in the ocular regions defined by the two circles when assessing goggles for protection against droplets. No account shall be taken of any such colouration up to a distance of 6 mm inside the edges of the eye-protector;

b) face-shields cover the eye-region rectangle of the appropriate head-form as described in 10.2.2.2 of EN 168:2001 as assessed in accordance with 10.2 of EN 168:2001.

Additionally, face-shields for protection against splashes of liquids shall have a viewing area with a minimum vertical centre-line depth of 150 mm when mounted in the appropriate housing.</td><td>NA for droplets (only for googles)

Applicable for splashes of liquids. Propose to use actual observation method instead of on head form</td></tr>
<tr><td>7.2.5 Protection against large dust particles</td><td>NA</td></tr>
<tr><td>7.2.6 Protection against gases and find dust particles</td><td>NA</td></tr>
<tr><td>7.2.7 Protection against short circuit electric arc</td><td>NA</td></tr>
<tr><td>7.2.8 Lateral Protection</td><td>NA</td></tr>
<tr><td>7.3 Optional requirements</td><td></td></tr>
<tr><td>7.3.1 Resistance to surface damage by fine particles</td><td>NA</td></tr>
<tr><td>7.3.2 Resistance to fogging of oculars</td><td>NA</td></tr>
<tr><td>7.3.3 Oculars with enhanced reflectance in the infrared</td><td>NA</td></tr>
<tr><td>7.3.4 Protection against high speed particles at extremes of temperature</td><td>NA</td></tr>
</table>

Any end user specific requirements	
	To be discussed
Wipe Down with IPA	
Sterility Test	