Info sheet on additively manufactured devices and services from TÜV SÜD in times of the Covid-19 pandemic

Product Service

Date of Publication: 08th of April 2020

General information

In the current situation of the Covid-19 pandemic there are different types of devices which are being produced by additive manufacturing (AM) technologies. One example is *personal protective equipment* (PPE, e.g. facemasks and shields).

The intended use of the device defines the relevant regulation. If the device is classified as PPE (protects user from particles, droplets or other harm) then the PPE-Regulation (REGULATION (EU) 2016/425) has to be applied. If the intended us of the device is not a PPE, then different regulations have to be considered.

For facemasks and shields TÜV SÜD cannot offer any testing and certification services, due to lack of accreditation for these product categories. However for face masks the ZLS (Zentralstelle der Länder für Sicherheitstechnik) approved a reduced testing scheme (incl. EN 149) for Germany (link) and at the time of publication of this document, there were three approved labs for this reduced scheme, namely Institut für Arbeitsschutz der DGUV (IFA), DEKRA Testing and Certification GmbH and TÜV NORD CERT GmbH.

For face shields there is no reduced testing scheme. These PPE have to follow the full conformity assessment procedure of the PPE-Regulation. Possible steps along the conformity assessment procedure can be (non-exhaustive list):

- 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 (Example testing labs are the ECS GmbH or the Prüf- und Forschungsinstitut Pirmasens e. V.)
- Preparing of the Technical Documentation (Annex III of PPE-Regulation)
- Internal production control (Module A) of Annex IV (example excerpt of this annex: “manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE”)
- CE-self declaration of conformity structured after Annex IX

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

What TÜV SÜD can offer for Additive Manufacturing / 3D Printing

Furthermore, TÜV SÜD offers services (down below) for all kinds of additive manufacturing (AM) technologies, products and parts. For inquiries about AM services please contact: am@tuev-sued.de

Industrial AM production site – Certification after DIN SPEC 17071

With this TÜV SÜD certification scheme on state-of-the-art standards we can help you with:

- Quality management for AM processes
- Quality assurance for industrial applications
- Reproducible and traceable processes
- Controlled material handling

A list of certified industrial AM sites can be found under the following link.

Info sheet on additively manufactured devices and services from TÜV SÜD in times of the Covid-19 pandemic

Date of Publication: 08th of April 2020

Checklists

TÜV SÜD has prepared free checklists and considerations for additive manufacturing devices to fight challenges of the Covid-19 pandemic.

In this document, we list the most important standards and regulations – general and AM-specific. Based on our AM specific trainings and the above-mentioned standards, we created checklists for:

- General considerations for the user of AM devices (e.g. Industry worker, cashier)
- AM geometry considerations for product/part owner/OEM (e.g. for designers, engineers)
- AM workflow self-assessment of key elements for manufacturers of AM devices

These checklists can be found in the appendix II of this document.

Technical reports for new and reengineered AM products:

A technical report on state-of-the-art documents (standards, white papers, guidelines). This assessment can include, but is not limited to:

- Workflow / Build process
- Credibility of transfer (existing designs adapted for AM)
- Design and material
- Functional description
- Basic requirements (depending of regulation)
- Risk management
- Technology

For this technical report you can find the template for issuing in the appendix III of this document.

Technical meetings

A technical meeting on state-of-the-art standards and expert knowledge. This meeting can provide, but is not limited to:

- Regulatory knowledge
- Technical information on:
  - Technology
  - Risks
  - Qualification and Validation
  - Quality assurance

Training

Trainings on a broad field of topic can be found under this link. The trainings portfolio includes but is not limited to:

- Design Basics / Design Validation in AM
- Quality and production management in AM
- Risk analysis and management in AM
- Process validation in AM
- Specification for purchased AM parts
- And More

If you have any further questions or comments, we are happy to help.

Appendix I:
Relevant standards and regulation

AM standards

- DIN SPEC 17071: Additive manufacturing — Requirements for quality-assured processes at additive manufacturing centres
- ISO/ASTM 52901: Requirements for purchased AM parts
- ISO/ASTM 52910: Guidelines for additive manufacturing design
- VDI 3405 Blatt 3.4: Additive manufacturing processes - Design rules for part production using material extrusion processes
- ISO/ASTM 52904: Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications

Non-AM standards, but relevant for AM devices

- 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 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 ISO 13688:2013 Protective clothing - General requirements
- EN ISO 22301:2019 Security and resilience - Business continuity management systems – Requirements
- ISO 22395:2018 Security and resilience - Community resilience - Guidelines for supporting vulnerable persons in an emergency
- ISO 22320:2018 Security and resilience - Emergency management - Guidelines for incident management
- ISO 22316:2017 Security and resilience - Organizational resilience - Principles and attributes
- ISO 31000:2018 Risk management – Guidelines

Non-AM standards, not relevant for AM devices

- EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

Appendix II:
Checklists and considerations

Product Service

Checklists and considerations for additive manufactured devices helping to fight the COVID-19 crisis

1. General considerations for the user of AM devices (e.g. Industry worker, cashier)

2. AM geometry considerations for product/part owner/OEM (e.g. Designers, Redesigners and Engineers, not relevant for users)

3. AM workflow self-assessment of key elements for manufacturers of AM devices

4. Possible risks along the workflow

Appendix II:
Checklists and considerations

Product Service

1. General considerations for the user of AM devices (e.g. Industry worker, cashier)

DISCLAIMER: All elements of the following list can be found in the standards listed above (appendix I). This list just gives a basic and not comprehensive insight on considerations needed for AM devices and it can be necessary to consider more standards or regulations, which are not listed in this list or homepage.	
Component application/category	
What quality of AM parts does the user require: A) High industrial quality from a certified production site after state-of-the-art-standards with traceable, quality assured processes ⇨ TÜV SÜD certified contract manufacturers after PPP11001 should be considered Or B) Prototyping quality ○ Any AM production site can be considered	
Is it a component of a personal protective equipment (PPE, e.g. face mask/face shield) or a component of a different device? (This divines the regulatory framework it has to follow) e.g. PPE ➔ REGULATION (EU) 2016/425	
Material considerations Is the printed material the same as in the original device? If not: - Does the processed material have the same or similar properties? - Is there objective evidence, that the new material complies with the necessary regulation (e.g. for PPE the Essential Health and Safety Requirements)	
If the component is a PPE, does it follow the “REGULATION (EU) 2016/425”? Especially the Annex II: Essential health and safety requirements? Furthermore, the EN 149 should be considered. For this accredited labs are: - Institut für Arbeitsschutz der DGUV and - DEKRA Testing and Certification GmbH - TÜV NORD CERT GmbH Further information: The German authorities responsible for the PPE (named ZLS) accepted for a certain period two ways of bringing masks into Germany: - Either the product has a national approval from Canada, USA, Japan, China, Australia) or - The product passes an abbreviated test according EN 149 See also: http://www.zls-muenchen.de/aktuell/index.htm#2019 Basis for this approach of the ZLS is the Guidance from the European Commission: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.LI.2020.079.01.0001.01.ENG Some standards related to these products are for a certain period for free https://www.cencenelec.eu/News/Press_Releases/Pages/PR-2020-003.aspx	

Appendix II:
Checklists and considerations

2. AM geometry considerations for product/part owner/OEM (e.g. Designers, Redesigners and Engineers, not relevant for users)

DISCLAIMER: All elements of the following list are a small part of our "AM Quality and Production Management" training. This list just gives a basic and not comprehensive insight on the possible design considerations for AM devices and there are more quality assurance steps needed for a holistic quality management. To get a comprehensive overview different trainings can be booked under this link.	
Sudden increase in cross-section *Whenever possible, sudden change in cross-section should be avoided*	
90° corners *Whenever possible, 90° angles should be avoided*	
Round channels *The cross-section of cavities or internal channels shall be shaped in such a way, that support structures are excluded*	
Enclosed volume *Enclosed volume or cavities with no or just one opening shall be avoided. Alternatively, access area to be reclosed shall be defined.*	
Dead ends *Dead ends, narrow openings and channels with a sharp bend shall be avoided.*	
Solid material *Large blocks of solid metal increase the part's cost significantly.*	
Sharp edges *Sharp edges should be avoided.*	
Milled surfaces (threads, holes, flanges) *Mounting areas requiring a higher resolution require machining. Thus, a clamping of the part shall allow for machining of such areas*	
High aspect ratio *Prominent features sticking out of the part with a high aspect ratio (thin cross-section and long shape) shall be avoided.*	
Wall thickness *Features below 1 mm shall be agreed with the manufacturer, in particular if it serves a purpose (e.g. pressure, loaded).*	
Minimum gap distance *Built-in connectors (e.g. hinges, gearbox) require spacing. Also, long slits or holes with a high aspect ratio shall be avoided.*	
Part dimensions *Part dimensions shall be lower than the build chamber (otherwise component has to be split in parts)*	

Appendix II:
Checklists and considerations

Product Service

3. AM workflow self-assessment of key elements for manufacturers of AM devices

DISCLAIMER: All elements of the following list are a small part of our "AM Quality and Production Management" training and is based on the DIN SPEC 17071. This list just gives a basic and not comprehensive insight on the possible workflow considerations for AM devices and there are more quality assurance steps needed for a holistic quality management. To get a comprehensive overview, different trainings can be booked under this link.	
Manufacturability Assessment	
Design Check / Compatibility with inhouse AM technology	
Check of dimension and tolerances	
Check of material / material properties	
Quality Assurance	
Trained and skilled personnel	
Documentation for all used manufacturing parameters stored (traceability)	
Qualified systems and processes (Installation, Operational and Performance Qualification)	
Data Preparation	
Error-free processability of 3D-data (Data repair software)	
Documentation of the STL conversion parameters	
CAM processes reproducibly managed? Standard Operating Procedure or Work Instruction?	
Archiving of all data (e.g. 3D-data, positioning)	
Feedstock management	
Suitability of material properties ensured	
Feedstock batch controlled	
Reproducible and contamination free feedstock management	
System-related pre-processing	
System preparation documented (e.g. Work Instructions, Checklists)	
Process guidance	
Production run monitoring (e.g.: in-process monitoring tools, manual visual inspection)	
Archiving of the in-process monitoring data	
Log-data of the production run parameters archived	

System related post-processing (technology dependent)	
Implementing and following the Work Instructions for part removal	
Implementing and following the Work Instruction for cleaning the machine	
Part specific post-processing	
Processing of the part to remove all residual powder, process residues or support structure	
Mechanical part specific post process (e.g. machining) controlled and documented	

4. Possible risks along the workflow

DISCLAIMER:

All elements of the following list are a small part of our “AM Quality and Production Management” and “Risk Assessment” training. This list just gives a basic and not comprehensive insight on the possible risks along the AM workflow and there are more risks to consider for a holistic risk management.
To get a comprehensive overview, different trainings can be booked under this link

Possible risks along the AM workflow:

- Wrong handling of feedstock (e.g. powder or filament) which leads to contamination and/or degradation of material
- Wrong preparation of the AM-System (e.g. Insufficient cleaning of building chamber, no checking of Filter condition, wrong set-up of build plate)
- Wrong post-processing of parts (e.g. Insufficient support removal, Insufficient cleaning of part (e.g. powder, process aids or process residues), wrong/insufficient sterilization
- Wrong storage of relevant data to ensure a clear traceability (e.g. 3D CAD File and/or Process monitoring data/pictures)
- Wrong process parameters (e.g. scanning, building chamber atmosphere)

Appendix III:
Template to issue a technical report

Product Service

Template to issue technical reports on prototypes of 3D printing products due to the breaking supply chains in the corona pandemic

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. As soon as you have sent us the order including a printed product, we will create a technical report within five working days.

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.

1. Elements of AM workflow and crucial KPIs
1.1. General information
1.2. Quality assurance
1.3. Data preparation (parameter settings)
1.4. Feedstock management
1.5. System-related pre-processing
1.6. Process guidance
1.7. System related post-processing
1.8. Part specific post-processing
2. Risk assessment by Manufacturer
3. Providing sample of 3D printed part
4. Next steps necessary for PPE (non-exhaustive list)

Appendix III:
Template to issue a technical report

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			

Appendix III:
Template to issue a technical report

3. Providing sample of 3D printed part

Sample part must be sent to TÜV SÜD AMA for assessment of design and production capabilities.
Address:
TÜV SÜD AMA
Ridlerstraße 65
80339 München
Germany

4. Next steps necessary for PPE (non-exhaustive list)

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.