Version	Date	History of changes
1	270320	Initial version

Written by Date Signature		Approved by Date Signature	

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1. General aspects

1.1. Application form

SPENTYS INFORMATION					
Project name	**Manufacturer**	**Contact information**	**Authorized representative**	**Conformity assessment procedure**	**Notified Body**
Face shield mask Spentys	Spentys SA Rue Saint-Denis 120 1190 Brussels BE	Florian DE BOECK florian@spentys.com +32 479 721 321 QA/RA Manager	/	The conformity assessment follows Annex VIII (custom-made medical devices) of the MDR EU 2017 745 Regulations. Spentys has a quality system in place based on EN ISO 13485:2016.	Class IIa

Table 1. Spentys informations

1.2. General information concerning the product category

Face shield masks are used to protect the face, especially the eyes and skin, of the wearer from mechanical, thermal and chemical risks in the work context.

In this technical file, the objective is to develop the face shield masks that are used in this context of covid-19 by the medical staff.

All responsibilities for the utility of the masks are towards hospitals and clinics and their employees. The target population is the medical workers.

1.3. Classification

According to the *Article 3* of the REGULATION (EU) 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC:

> *'personal protective equipment' (PPE) means:*
> *(a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;*
> *(b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;*
> *(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use;*

The Face Shields is then considered as a personal protective equipment (PPE) because they are intended to be used protection against contaminated fluids.

The PPE shall be classified according to the risk categories set out in Annex I.

> *'Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.'*

Category I includes exclusively the following minimal risks:

(a) superficial mechanical injury;

(b) contact with cleaning materials of weak action or prolonged contact with water;

(c) contact with hot surfaces not exceeding 50 °C;

(d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);

(e) atmospheric conditions that are not of an extreme nature.

Category II includes risks other than those listed in Categories I and III;

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:

(a) substances and mixtures which are hazardous to health;

(b) atmospheres with oxygen deficiency;

(c) harmful biological agents;

(d) ionising radiation;

(e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;

(f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less;

(g) falling from a height;

(h) electric shock and live working;

(i) drowning;

(j) cuts by hand-held chainsaws;

(k) high-pressure jets;

(l) bullet wounds or knife stabs;

(m) harmful noise.

The Face Shields are class II PPE.

1.4. Facilities and critical subcontractors

1.4.1. Design and manufacturing facilities

Design	***Production***	***Packaging***	***Distribution***	***Quality System***
Spentys SA Rue Saint-Denis 120 1190 Brussels BE	Spentys SA Rue Saint-Denis 120 1190 Brussels BE	Spentys SA Rue Saint-Denis 120 1190 Brussels BE	Spentys SA Rue Saint-Denis 120 1190 Brussels BE	Spentys SA Rue Saint-Denis 120 1190 Brussels BE

Table 2. Design and manufacturing facilities

1.4.2. Critical subcontractors' facilities

Subcontractor	Address	Activities	Certification	Approval & Contracts
TreedFilament, Healthfil subdivision	Damiano Brivio Sales and Marketing Manager Mob. + 39 3487604846 Address: Via Messina 103, 20831 Seregno (Italy) http://healthfil.com/ Binder Benelux & France Industriegebied Ganzenbol - Fabriekstraat 56D B- 2547 Lint / Belgium. Tel: +32 (0)3 - 460 17 80 www.binder.de https://hookandloopblog.com/	Supplier and manufacturer of raw materials for FDM 3D printers	**CE Marking**	Y See Healthfil Folder
Company name: Ultimaker B.V. Dutch Business Registrations: 56793138 VAT number: NL8523.04.158.B01	Stationsplein 32, 3511 ED Utrecht Tel: +31 (0) 88 383 4000 E-mail: info@ultimaker.com	Supplier of Printers	**CE Marking** Complies with Annex I of the European Low Voltage Directive 2014/35 / EU and the following directives: - 2014/30/UE compatibilité électromagnétique - 2011/65/UE RoHS	Y See Ultimaker Folder
Imatex	SLUIZENSTRAAT 83 2900 SCHOTEN - BELGIE +32 (0)3/658.39.44 info@imatex.be www.imatex.be	Supplier of plexiglas sheet		
Coronati Consulting Laboratory	Via L. Gavioli, n. 3 (laterale di Via di Mezzo) 41037 Mirandola (MO) Tel. 0535.611533 Fax 0535.410441 E-mail: info@coronaticonsulting.it	Bio-Compatibility Test (according to ISO 10993)	- Certificat ISO 9001:2015 - Certificat ISO 13485:2016 - Significant dell'Accreditamento ISO/IEC 17025:2005 - List of accredited test (Rev.06) 31-07-17 - Accreditamento Certificate ISO-IEC 17025	Y See Coronati Folder

Table 3. Critical subcontractors' facilities

2. Device description

2.1. General description

A face shield is a device to protect the wearer's entire face (or part of it).

Protective masks are part of the PPE (Personal Protective Equipment) essential in certain work environments. They guarantee protection of the eyes and skin of workers against some mechanical, thermal and chemical risks.

Personal protective equipment (PPE) is a device or method intended to be worn or held by a person in order to protect against one or more risks likely to threaten the safety or health of a person mainly at work.

PPE is divided in three categories:

- class I: work equipment covering minor risks,
- class II: work equipment covering significant risks,
- class III: work equipment covering serious risks with irreversible or fatal effects.

The choice of PPE is based on the risks to be prevented, the working conditions and the users, and this very precisely (tasks carried out by the user, size of the user, composition of the products used, standards in effect). The work doctor can also be consulted in the choice of PPE.

PPE must be worn when risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures for the organization of work.

The equipment shall be used to reduce exposure to harmful physical, chemical or biological agents as far as possible. If they cannot eliminate a hazard, they can at least eliminate or significantly reduce the risk of injury.

In medical applications, "face shield" refers to a variety of devices used to protect a medical professional during a procedure that might expose them to blood or other potentially infectious fluids and also against exposure to potentially infectious materials.

2.2. Intended use, users, patients, environment

Intended use: Face shield masks are indicated to protect the face of the medical staff from possible contaminated fluids in this context coming from patients (suspected or confirmed) of covid-19.

Intended users: The face shield masks are intended for use by clinicians as a solution to the shortage to provide the necessary care to patients who need it while reducing the risk of possible contamination.

2.3. Warnings

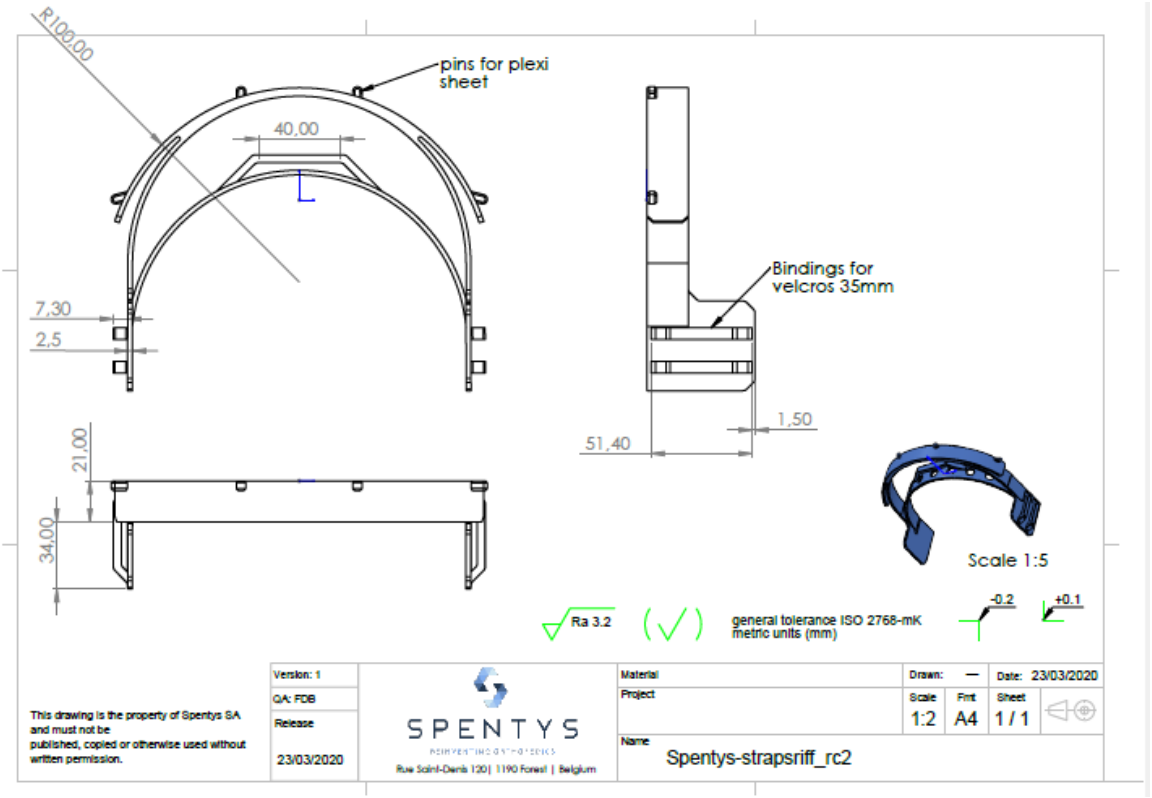
Think Safety Glasses AND Face Shield both.

Typical safety eyewear doesn’t provide the necessary protection required for handling liquid, chemical adherents and or with body fluids.

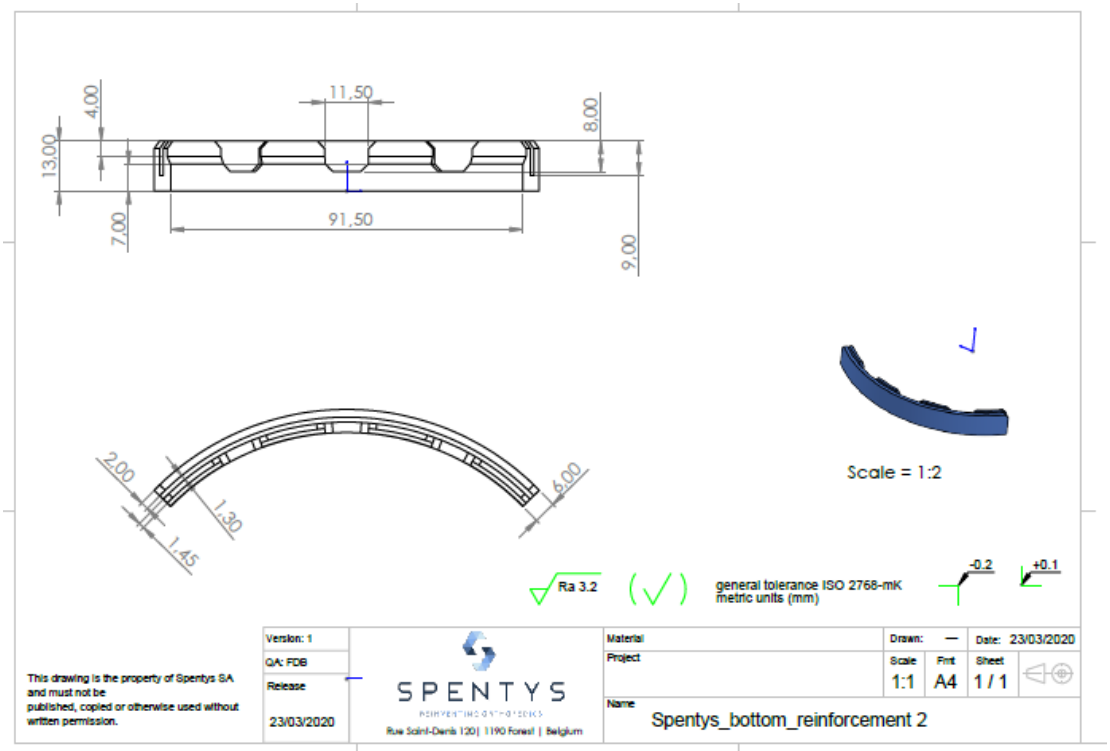
Face shields do an excellent job of providing extra eye and face protection from a variety of dangers. However, you should always wear safety glasses under your face shield because the bottom and sides of face shields typically have gaps: splash passing through these gaps can contact your eyes or your skin.

So, you should wear safety glasses and face shields!

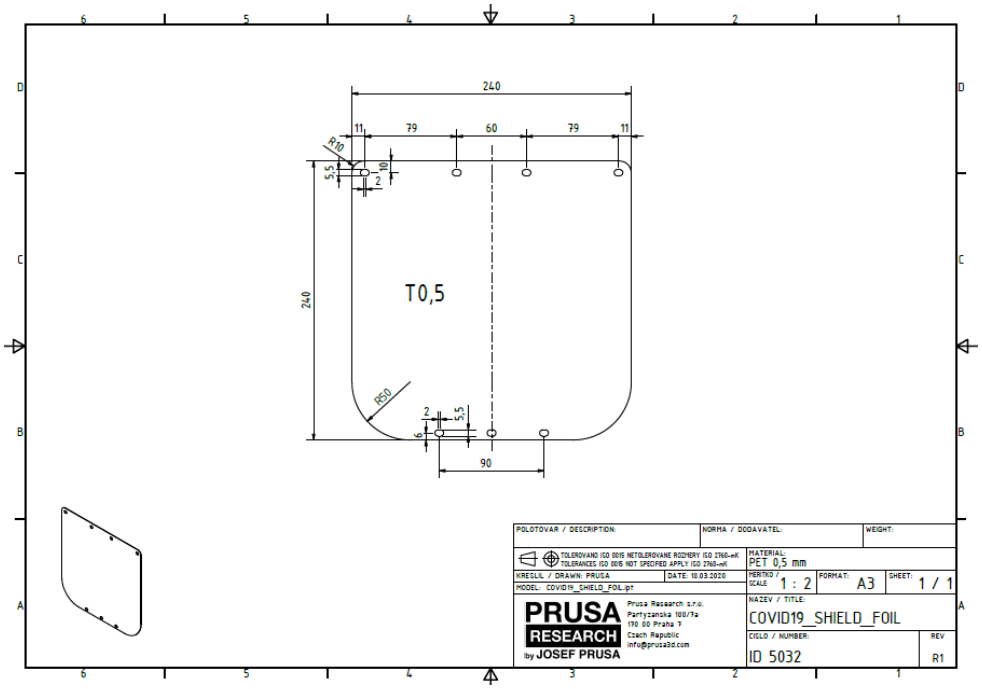
2.4. Product drawings



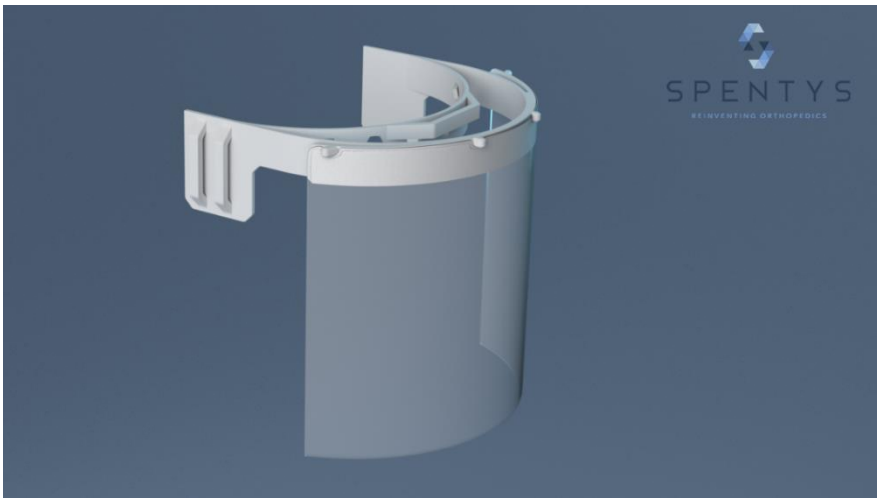
Picture 1. Spentys Face Shield



Picture 2. Spentys Reinforcement base



Picture 3. Shield foil



Picture 4. Mask rendering

All technical aspects are explained in the following sections.

2.5. Product design specifications

Face Shield specifications
4 pins for Shield foil
Shield foil's thickness: 1mm
2 bindings for velcro in each side Structure: PETG/PP
Shield foil: APET

Table 4. Face shield's specifications

Usability specifications	
Specifications	**Solutions**
Easy to wear	2 bindings to adjust.
Protect the face	Plexiglas sheet
Durable, waterproof, moisture-resistant, radiolucent, non-flammable, nontoxic medical device	Choice of material
Compact, light	Design and materials

Table 5. Usability specifications

3. Essential principals and evidence to conformity

3.1. Identification of standards

All applicable standards (European or other standards used by manufacturers), including year of reference, are listed in the table below

Standards	Function	Title
ISO 13485:2016	Quality Management	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2012 (New version-2019)	Risk Management	Medical Devices. Application of risk management to medical devices
EN 166:2002	Specification	Individual eye protection

Table 6. References and titles of the standards

3.2. Essential requirements

The essential requirements checklist is provided in the document: Essential Requirements Checklist.

3.3. Declaration of conformity

Declaration of conformity is provided in the document: Declaration Of Conformity.

4. Risk management

Report on Risk analysis can be found in the Risk Management File that identifies:

- The team members,
- The risk management plan,
- The risk identification list,
- The analysis performed on the product FMEA (product, various components...),
- Explanation of the acceptable risk levels and when mitigation is required,
- Conclusions based on risk benefit analysis.

The following tables summarize the number of risks that have been into account and the rank after mitigation iterations.

Product FMEA	Acceptable	Moderate	Intolerable
Initial risks	0	24	0
Mitigation ongoing	/	/	/
Final risks	24	0	0

Table 7. Number of risks after mitigation iteration

It is shown that no (0) risk has been closed with Moderate or Intolerable level.

4.1. Overall residual risk evaluation

After the assessment and evaluation of the risks and the application of each measure, within the frame of the state of the art, the overall residual risk is considered as acceptable for use in normal conditions while fully respecting the directions and precautions described in the IFU. A major reason why such an approach could be successfully applied in this case is that all material used are well-characterized off-the-shelf materials known to be biocompatible.

4.2. Risks/Benefits Analysis

Based upon the presented results and considering the available data, it can be concluded that the Face shield does not pose a concern to human health for the intended use and if prescribed and used by trained healthcare professionals. The risk/benefit largely lies above the risk-benefit threshold, so users may expect more benefit than risk in any cases.

5. Summary of design verification/validation

The development of the Face Shield was driven by the defined user requirement specification.

5.1. Design and properties

5.1.1. Design

- Headband: thickness of 21mm according to the standard EN166.
- Headband is adjustable with the two biddings for velcro.
- Design to provide the best user comfort: no protrusion (Printing procedure and Quality check)
- The field of vision is not disturbed other the width of the mask: 240mm.

5.1.2. Properties

- Hard and durable material. Charpy impact strength = 1 - 10 kJ/m² at 20 °C
- Max Service Temperature: 60°C
- Coefficient of thermal expansion: [7E-5;8E-5] (1/K) at 20°C
- Flammability: UL94HB

5.2. Biocompatibility

The PETG from Smartfil. The PETG from Smartfil is made of a PETG (Polyethylene terephthalate Glycol) at 99%. This component is well known and used in the food and medical field. According to the MSDS of the PETG, provided by the supplier (refer to MSDS PETG from Smartfil):

- The preparation is not classified as dangerous according to (CE) nº 1907/2006, Article 31.
- The preparation is considered harmless for human health as it is and when exposed to normal and predictable production process and storage. According with EU directives it is not dangerous.
- The preparation is normal storage and processing conditions is inert and does not show environmental hazard.
- At ambient temperature the product is not irritating and does not release harmful smokes. The measures indicated in the Test and MSDS documents are referred to a critical situation (fire, wrong process, conditions).
- Density [g/cm3]: 1.27 (ASTM D792)
- HDT [C°]: 70 (ASTM D648)
- Vicat softening temp. [C°]: 85 (ASTM D1525)
- Flexural modulus [MPa]: 2100 (ASTM D790)

The Polypropylene (PP) from Smartfil. The PP from Smartfil is composed of polypropylene polymer: 1-butene, ethene polymer, 1-propene – 99.5% (CAS:25895-47-0). PP component is well known and used in the medical field. According to the MSDS of the PP, provided by the supplier (refer to MSDS PP from Smartfil):

- The preparation is not classified as dangerous according to Regulation (EC) No 1272/2008.
- The preparation is not classified according to the CLP regulation.
- The preparation is not classified according to the directive 67/548/CEE or Directive 1999/45/CE.
- The preparation is considered harmless for human health as it is and when exposed to normal and predictable production process and storage. According with EU directives it is not dangerous.
- The preparation is normal storage and processing conditions is inert and does not show environmental hazard.
- At ambient temperature the product is not irritating and does not release harmful smokes. The measures indicated in the Test and MSDS documents are referred to a critical situation (fire, wrong process, conditions).
- Density [g/cm3]: 0.9 (ISO 1183)
- HDT [C°]: 62 (ISO 75)
- Vicat softening temp. [C°]: 107 (ISO 306)
- Tensile modulus [MPa]: 2410 (ISO 178)

5.3. NF EN 166: Personal eye protection

The Face Shield technical file is based on the EN 166 standard. Spentys follow as much as possible the recommendation of the standard. The Spentys face Shield will be able only for the medical professionals during the period of crisis.

Requirement	Norm references	Spentys
Construction and material	6.1	Printing procedures and Quality check.
	6.2	Biocompatibility tests.
HeadBand	6.3	Design.
Field of view	7.1.1	Design: APET sheet of 240mm wide, no ocular.
Transmission factor	7.1.2.2.2	Not applicable: "The evaluation of the transmission factor is only necessary if the eye protection consists of a goggle mask or a face shield and may be equipped with filter(s) for use against optical radiation" No filter on Spentys Face Shield.
Reinforced solidity	7.1.4.2.2	Material Datasheet. In regard of the emergency and the very low probability of being in this situation, Spentys trusts the material datasheet and previous tests.
Heat stability	7.1.5.1	Material Datasheet. In regard of the emergency and the very low probability of being in this situation, Spentys trusts the material datasheet and previous tests.
Corrosion	7.1.6	Not applicable: materials are not corrosive.
Flammability	7.1.7	Material Datasheet. In regard of the emergency and the very low probability of being in this situation, Spentys trusts the material datasheet and previous tests.
Liquid projections	7.2.4	Design: plexiglas sheet is large enough to cover the user's face.
Marking	9.3	No mark needed.

5.4. Software validation

5.4.1. Solidworks

The software used in the modelling process is Solidworks.

Solidworks is the modelling software which can create, edit, analyse, document, make, animate, and translate curves and surfaces NURBS as well as solids, point clouds and meshes. It has no limit in terms of complexity, degree or size, apart from those of your hardware. Thanks to the Solidworks interface, stl 3D model files can be created.

6. Manufacturing information

6.1. The printing steps

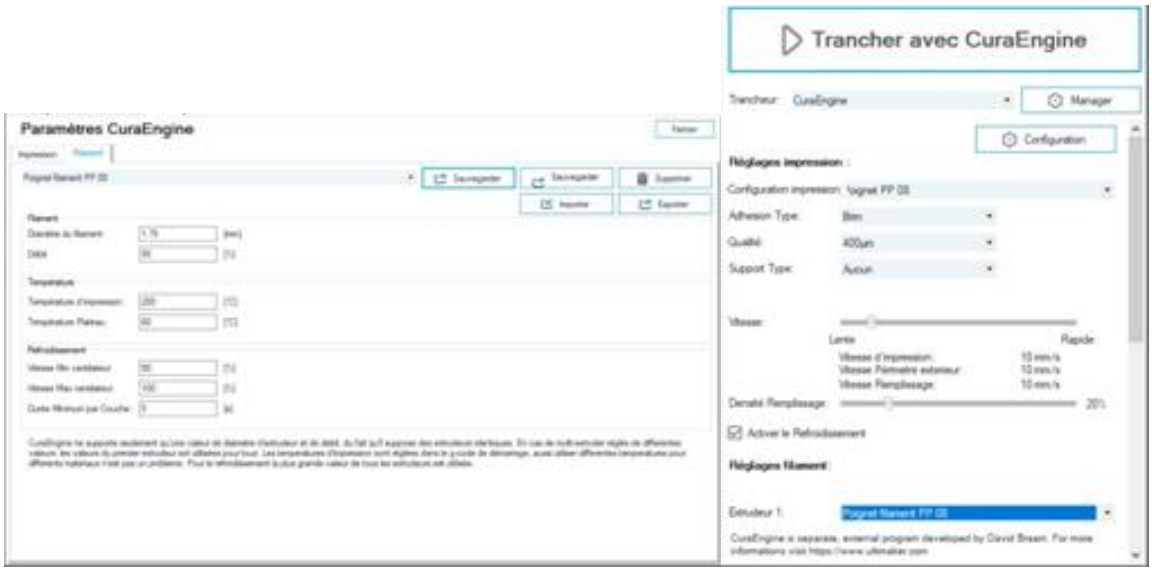
6.1.1. The 3D printing

The 3D printer used for the manufacturing has been specially developed for this application with the Ultimaker Company, to assure the stability and security of the 3D printing process. Each component in contact with the raw material has been analysed and certified biocompatible.

The 3D printing technique used is, Fused Deposition. The Ultimaker 3 expanse and Ultimaker 5 are CE marked and are compliant with the regulations laid down in annex I to the European Directive of low-voltage 2014/35/EU and the following directives: 2014/30/UE Electromagnetic compatibility, 2011/65/EC RoHS. For more details on the description of the print operating, please refer to Spentys – General Description 3D Print.

6.1.2. Description of the 3D printing process

To print the face shield, all the printing parameters detailed as follow will be recorded:



Picture 5. 3D printing parameters

- The debit and the diameter are constant if the extruders are the same (between 95% and 100%, and 1.75 mm or 2.85mm)
- The printing temperature is chosen in the started gcode. It's the melting temperature of the filament (Printing temperature)
- The plate temperature allows the structure to stay on the plate.
- For cooling, the largest value of all extruders is used. This value is often maximal, 100%, because printed layers must be cooled quickly.
- The adhesion (Brim or Raft) has to be chosen. This parameter is used to adjust the first layer, in order to optimize the adhesion of the part on the plate by increasing the contact surface.
- The print speed is managed from a slider that will increase the overall speed of printing. A median setting is often preferred because the layers will have time to cool and harden before going to the next layer. The high speed will degrade the quality of details on the parts to be printed.

- The choice of density is important because it determine the resistance of the structure. The higher the filling is, the more resistance the part will be. But it is advisable not to exceed 70% of filling because the higher the filling is, the stronger the internal tensions will be and the risk of geometric deformation.
- All the parameters related to the retraction allows to extrude back the filament (to remove the filament from the head for example).

All printing parameters have been optimized and defined in advance to stabilize the printing process. For more details about the parameters, please refer to the Printing Characteristics and Parameters section. After entering the print parameters, now the parameters of the structure can be given.

- The thickness of the wall
- The XY distance and the Z distance
- The number of lines of contour and the distance contour of the brim have to be chosen
- The thickness of the brim or raft

It is Important to know how to use the printer, the calibration method, and how to do its maintenance.

In the SOP (Instruction - 3D Printer), all the terms of use of the printer will be found, as well as the security instructions, the method to install the spools and all the needed maintenance to keep the product in the good conditions.

6.4.3 Description of post-printing process

A post-printing process is also performed. Once the structure is printed, a trained Spentys staff will check the printing quality and correct the potential errors. This quality check is done after the end of the production. The operator uses the cutter to remove the imperfections; he must eliminate the roughness surface of the structure to avoid the risk of irritation and itching for the user.

6.2. The assembly steps

Once the 3D printed structure finished, we assembly each part of the mask. We fix manually the Plexiglas sheet on the four pins of the structure. A velcro band is fixed at the back. The quality of assembly is checked (visual, good holding...).

6.3. Description of delivery process

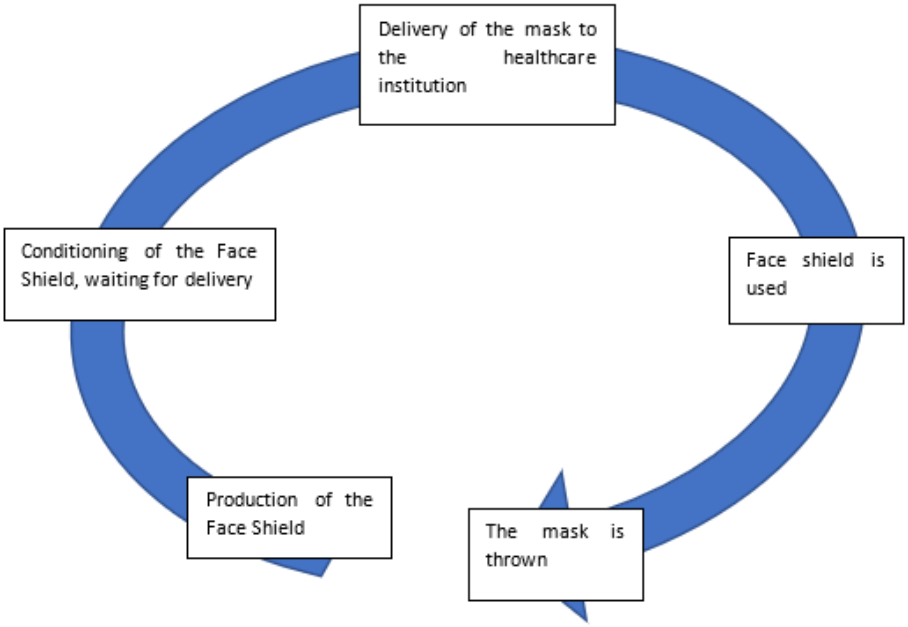
Once the Face Shield is assembly in the 3D printing factory, it must be delivered to the hospital. The masks are provided in a box which contains 20 to 50 face shields. The DOC, labels and IFU are inserted inside the package and the hospital address is written on it.

6.4. Other manufacturing information

6.4.1. Device lifecycle

The lifecycle of the Face Shield goes from its production to its destruction. The production of the mask as well as the conditioning and the delivery takes min 24-72 hours after the order has been made.

It is a single use device and it must be changed daily. After the use of the Face shield, the physician throws the device. The diagram below summarizes the entire lifecycle of the Face Shield:

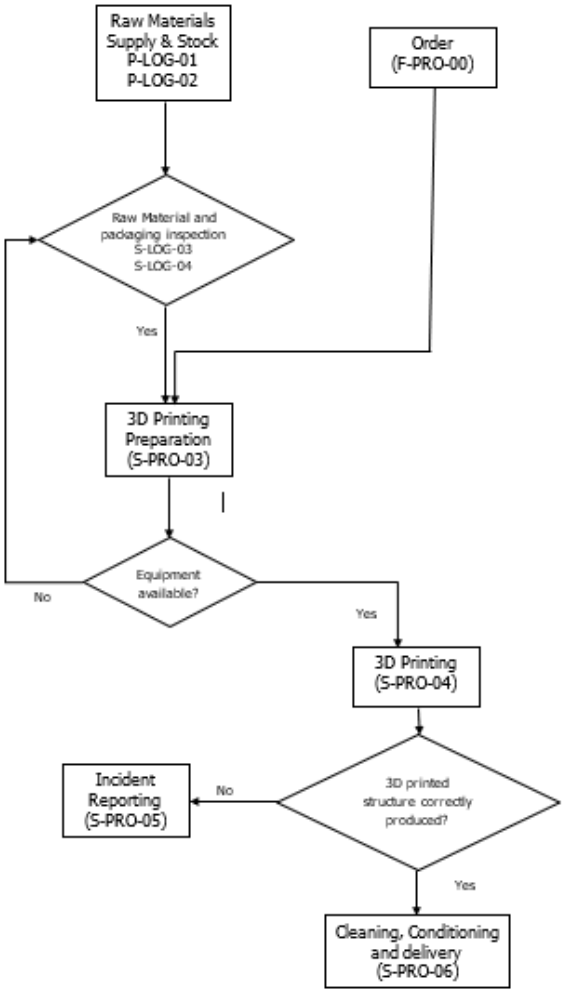


Picture 6. Face Shield LifeCycle

6.5. Manufacturing and Quality Control processes

All the Quality Control processes concern all the verification notified during the procedure (Procedure P-PRO-01).

All the steps of the production (from the order of the delivery) are explained in the Production procedure (PPRO01) and all the instructions related to these steps are detailed in the SOP of Production folder.



Picture 7. Production procedure

Other QC are performed by Spentys, to assure the stability of the whole process (QC on incoming raw materials, packaging, software and equipment qualifications and maintenance, etc. and recorded on a dedicated platform.

Manufacturing step	Reference
Production Procedures	**P-PRO-01**
Manufacturing Order	F-PRO-00
3D printing preparation	S-PRO-03 & F-PRO-03
Production	S-PRO-04 & F-PRO-04
Incident reporting	S-PRO-05 & F-PRO-05
Line Clean-Up / Quality Check	S-PRO-06 & F-PRO-06
Conditioning / Delivery	S-PRO-06 & F-PRO-06
Final QC and release	P-MON-3 & P-MON-04
Non-conformity (products and Production Management)	P-MON-01 & F-IMP-01
CAPA	P-IMP-02

Table 8. Documents refer to the manufacturing process.

6.6. Quality System summary

Spentys is a medical company dedicated to the design, production and distribution of medical devices. The Company is based in Brussels, Belgium.

The first series of products is based on the 3D scanning technology to gather measures of the patient's limb, then on the 3D modelling and 3D printing to design and produce the patient specific cast. These products will be registered as custom-made medical devices of class 1 non-sterile in the European Union.

The second series of products will be based on the 3D printing technology to design and produce face shield masks. These products will be registered as medical devices of class 2a non-sterile non-active in the European Union.

It is why Spentys must follow a strict Quality Manual (All details gathered in the document D-DOC-04 Quality Manual).

6.6.1. Quality Policy

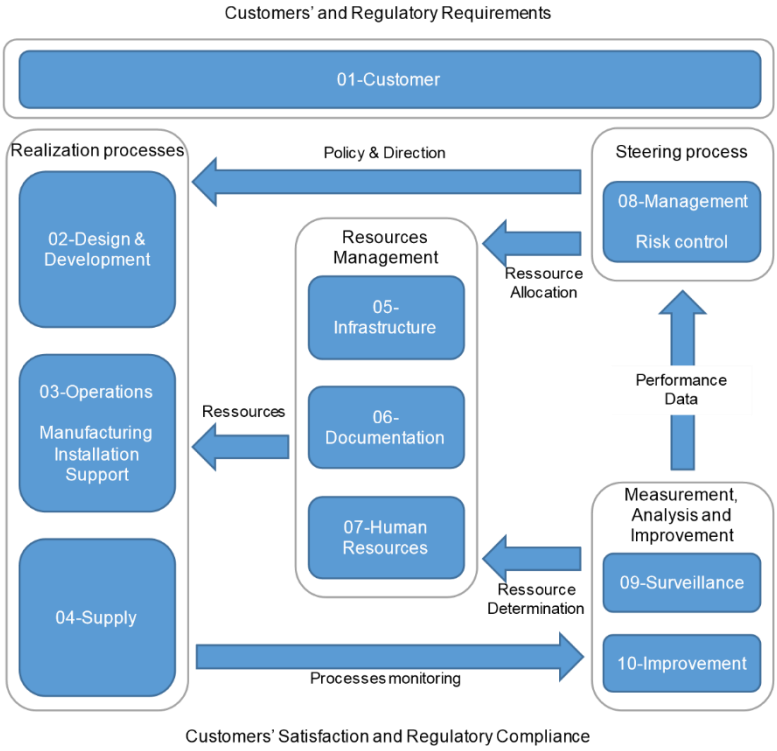
Spentys are engaged in a Quality Assurance program based on the international ISO 13485:2016. Our Quality Management System is covering: Design, production and distribution of medical devices.

As a company, Spentys strive for constant improvement throughout our business and would welcome a full and detailed audit by any of current and potential customers because these builds and develops mutual confidence.

Conscious of the competence and the dynamism of staff, Spentys get involved and help in building the Quality Management System successfully.

6.6.2. Quality Management System (QMS)

Here are the sections of the Spentys' Quality System (for more details, refer to D-DOC-04 Quality Manual).



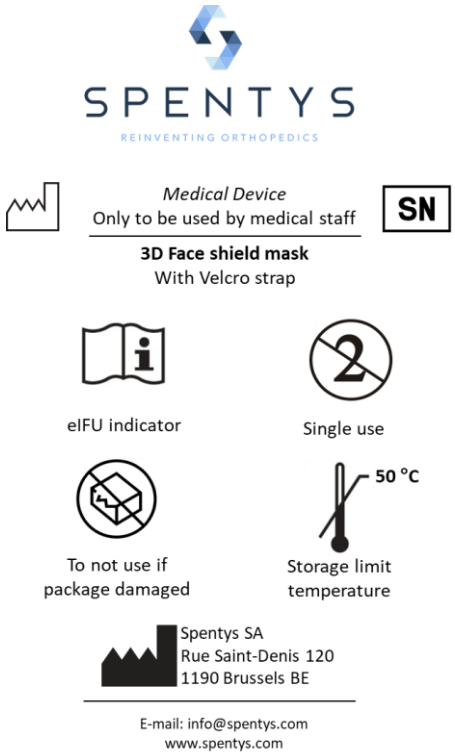
Picture 8. Sections of the Spentys Quality System.

7. Packaging & Labelling

7.1. Packaging description

Once the Face shield is printed in the 3D printing factory, it must be delivered to the hospital. The masks are provided in a box which contains 20 to 50 masks. The DOC, labels and IFU are inserted inside the package and the hospital address is written on it.

7.2. Labels



Picture 9. Labels Face shield protection

This label contains:

- ✓ The name / trade name of the medical device: “3D Face shield mask”
- ✓ The details to identify the device and its use: “3D Face shield mask”
- ✓ The name, address and information of the manufacturer:
  “Spentys SA
  Rue Saint-Denis 120,
  1190 Brussels BE
  Email: info@spentys.com
  www.spentys.com”
- ✓ The serial number of the device represented by the symbol: “ SN ”
- ✓ The fabrication date represented by the symbol “ ”
- ✓ The storage limit temperature represented by the symbol: " ".

- ✓ The contents of the package Warnings or precautions to be taken that are brought to the immediate attention of the user of the medical device:
  To not use if the package is damaged
  Read the Instruction for use
- ✓ An indication of the fact that the device is intended for single use: "Single use"
- ✓ An indication of the fact that the device is for use by medical staff: "Only to be used by medical staff"

The label is saved in "Spentys - Label Face shield mask"

7.3. Instructions for use

Purpose of product: Spentys Face Shields are designed to protect personnel against splashing in departments where maximum protection is required.

1. Place foam front against your forehead
2. Secure elastic band around the back of your head
3. Discard after use

The use of this or any PPE is to be used according to your specific facility policy.

7.4. Marketing

Spentys is present over the Network via our website. It is possible to find every details of our different projects: https://www.spentys.com/serving-hospitals-through-3d-printing.