TYPE: Operating Procedure
SUBJECT: Quality
CODIFICATION: SOP-003

DISCLAIMER:

This document is only provided to aid in the development of similar protocols for other organisations to use for the manufacture of Prusa face shields during the COVID-19 pandemic. This document has been authored for use only in the Cisco Reading face shield production process. Please use this as an overview to develop your own protocol.

This document has been developed with voluntary guidance from manufacturing professionals, it has however been developed in an extraordinarily short period of time and is not complete to a level that meets professional manufacturing standards. This document is supplied without warranty, no liability can therefore be accepted.

PROCEDURE FOR FLOW AND PROCESSING OF MATERIALS THROUGH THE MANUFACTURING UNIT

	Name/Function	Date	Signature
Author	Production program lead		
Reviewer	Health & Safety Representative for building/facility/organisation		
Reviewer	Volunteer/staff co-ordinator		
Approver	*NAME OF NHS STAFF MEMBER* *NAME OF NHS ORGANISATION*		

Date of Approved	Date of application	Date of document review

Versions history

Document version	Date	Type of modification
1.0	2020	First version
2.0	2020	Updates to enable external document release.

1 AIM (objective or purpose)

The purpose of this document is to describe the procedure that must be followed by all personnel to bring material into the manufacturing area, process the material, package and then remove from the manufacturing area.

2 SCOPE

This procedure applies to the end to end movement of material for manufacture related to the Face shield 3D printing process within the manufacturing unit. Here we outline the expected standards to be used within a clean non classified environment

This SOP is authored to be used during the COVID-19 pandemic to provide critical supplies to individuals working without professionally manufactured PPE.

3 OUT of SCOPE

This SOP is not suitable for use outside of the COVID-19 pandemic. This SOP is provided without warranty and is provided on an as-is basis as a ‘best we can do given the circumstances’ compromise.

4 RESPONSIBILITIES

It is the responsibility of all volunteers that may perform transport, cleaning, processing and packaging of materials within the clean room of the production unit to have read and understood this document. It is the responsibility of the project leadership to ensure that all volunteers that perform transport, cleaning, processing and packaging of materials within the clean room of the production unit have read and understood this document.

5 RELATED DOCUMENTATION

<RISK ASSESSMENT>
<TRAINING SESSION PPT>
SOP-001 Cleaning of materials in the production unit
SOP-002 Procedure for flow of personnel through manufacturing unit

6 ABBREVIATIONS

CNC: Clean Non Classified
PPE: Personal Protective equipment
PETG: Glycol Modified version of Polyethylene Terephthalate (PET),
PLA: Polylactic acid or polylactide (PLA), a thermoplastic polyester
QC: Quality control

7 MATERIALS AND REAGENTS

- Clinell Universal Wipes
- PETG 3D printing filament
- PLA 3D printing filament
- 0.5mm thick clear PETG sheets laser cut to specification according to the designs and instructions of the Prusa RCx face shield design (designs evolve quickly, please select the design which is most appropriate for your situation). This has become a 'defacto' 3D printed face shield design in Europe for use during the COVID-19 pandemic. This design has been approved for use by the Czech Health Ministry. https://www.prusaprinters.org/prints/25857-prusa-protective-face-shield-rc1
- 18mm wide buttonhole elastic (can be substituted with many other types of elastic)
- Food grade clear plastic zip lock bags (recommended minimum size 25 by 30 cm)
- Paper sheet printed double sided with important product information, QC checklist and assembly instructions – this forms the label for the product which is visible through the clear plastic zip lock bag (see appendix 3)
- Cardboard box
- Brown packaging tape
- Scissors
- File

8 OPERATING PROCEDURE

(See Appendix 1 for example Floor Plan)

Process Overview

1. All material is either provided by the manufacturer in sealed packaging or had been left in sealed packaging for 72 hours prior to assembly
2. Outer packaging materials are removed prior to entry into the CNC corridor
3. 3D printing filament is processed into 3D parts using either PLA or PETG
4. The part is assigned a QC checklist
5. 3D printed parts are removed and are manually processed to remove any stray filament
6. 3D printed parts undergo quality control inspection
7. Parts are packaged in food grade clear plastic zip lock bags
   7.1. 2x 3D printed parts (Headband and lower reinforcement)
   7.2. 18mm x 300mm wide buttonhole elastic
   7.3. 0.5mm thick clear PETG sheet laser cut to specification as a clear plastic visor
   7.4. Label with assembly instructions, important information & QC checklist
8. Finished packaging is packed into cardboard boxes and sealed with parcel tape
9. Finished packages are labelled and carried directly out of the CNC manufacturing area into a storage area for transportation

Inward flow of material between Outside – CNC manufacturing unit

1. Personnel must be doing the following;
   1.1. Materials must have their outer packaging opened in the lobby, outside of the clean side of the lobby area
   1.2. The materials are transferred by an individual on the clean side of the lobby area when they have reached step 1.13 (assessing gowning before proceeding into CNC access corridor) of SOP-002
   1.3. The individual completes steps 1 and 2.1-2.4 (movement into the Inbound PPE area) of SOP-002 carrying the product
   1.4. The individual cleans the internal product packaging with Clinell Universal Wipes and places in on the glass work top to dry
   1.5. The individual completes steps 2.5-2.7 (donning final PPE and assessing gowning before proceeding into the CNC manufacturing unit) of SOP-002
   1.6. The individual picks up the material, open door and enters the CNC manufacturing unit
   1.7. The material is taken to the relevant station

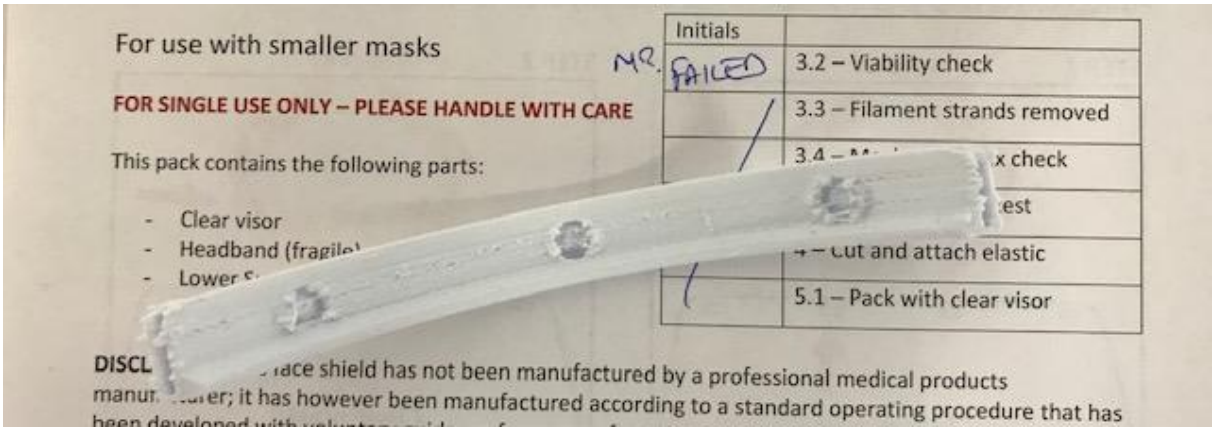
3D printing of components

2. Personnel must be doing the following;
   2.1. The headband is 3D printed according to the designs of the Prusa RCx (see appropriate version) face shield design.
   2.2. The two (2) 3D printed parts per face shield are removed from the build area

Quality inspection of 3D printed parts

3. Personnel must carry out the following tasks;
   3.1. Two (2) 3D printed parts are assigned a QC checklist, example below:

3.2. The 3D parts are inspected by an operator for defects significant enough to make the part no longer viable as a single use disposable face shield. Below is an example of a part which has failed the print process, the print head has extruded too much filament at the end of a continuous movement thus deforming the three holes:



The part should also be visually inspected for traces of oil or any other contaminant from the 3D printing process.

If this step cannot be completed to a satisfactory level of quality, the part is rejected and placed in the rejection box along with the QC checklist. The QC checklist is completed for this step.

3.3. 3D printed part ‘cleanup’

Freshly 3D printed parts require finishing by hand. This includes: removal of plastic support structures, and small imperfections of the 3D printing process such as strands of filament created during non-extruding moves; small ‘nodules’ created at the end of a non-extruding move; or pieces of ‘skirt’ from the first layer. Any of these imperfections can be sharp and could fall off, cut or irritate the user or contaminate their work.

Eye protection (Goggles or safety glasses which wrap around the eye) is already required at all times to operate within the production room. In addition to hygiene factors, this is due to the high risk of injury from pieces of plastic removed during the part cleanup process. These will be small, but sharp and jagged, and can be sent off in random directions by the person actively cleaning up parts, so may affect all other people in the space without warning.

3.4. After passing first QC inspection the 3D parts are processed by an operator to remove stray filament, using a file or the side of a closed pair of scissors (for safety). Particular attention should be given to the forehead facing surface of the head band.

3.5. The operator stops processing when they are satisfied that no pieces of filament could become dislodged through normal expected use as a single use disposable face shield.

If this step cannot be completed to a satisfactory level of quality the part is rejected and placed in the rejection box along with the QC checklist. The QC checklist is completed for this step.

3.6. The 3D parts are mechanically flexed gently by hand to beyond the bounds of expected movement during assembly and use to ensure that it does not splinter or break. An example of a part which snapped when mechanically flexed can be seen below/overleaf:

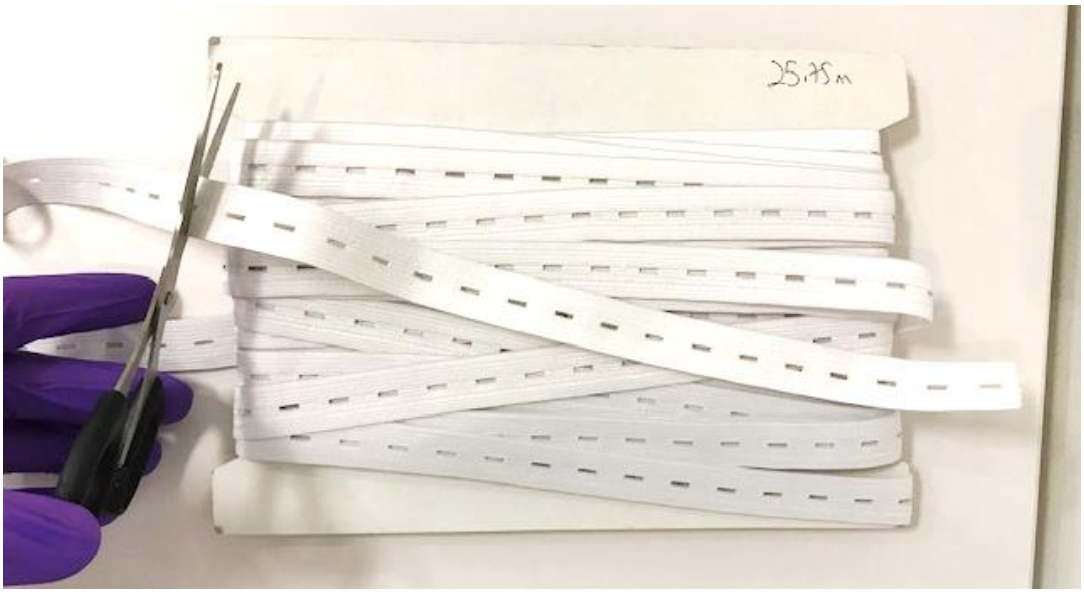
If the part breaks or splinters the part is rejected and placed in the rejection box along with the QC checklist. The QC checklist is completed for this step.

3.7. The six (6) protruding nodules on the headband of the 3D part should be mechanically stressed by hand to beyond the bounds of expected force during assembly and use to ensure that they do not splinter or break off. Examples of the process of manual stress testing:

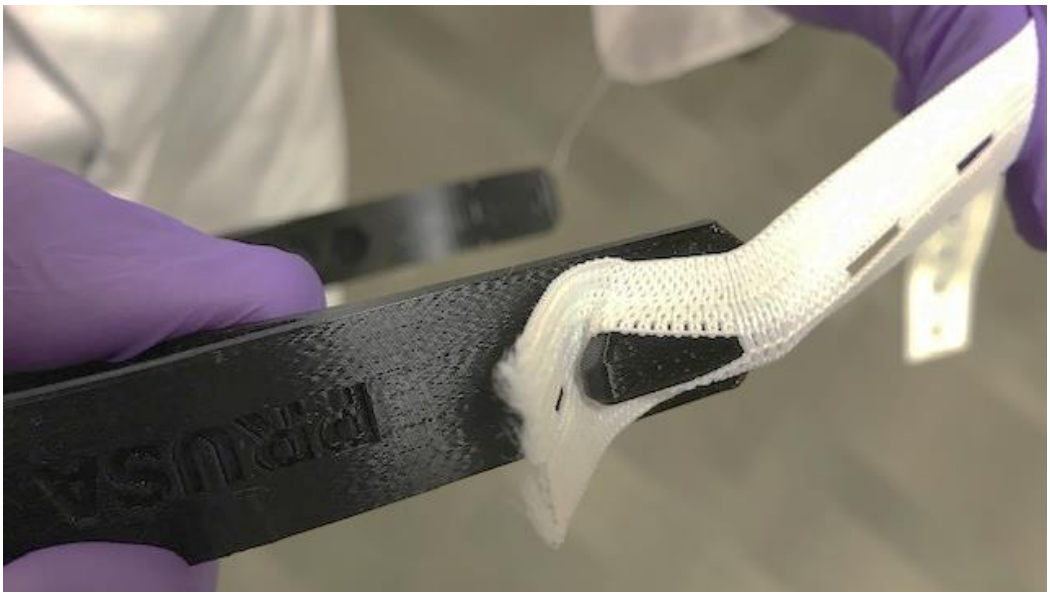
If the part breaks or splinters the part is rejected and placed in the rejection box along with the QC checklist. The QC checklist is completed for this step.

<u>Sub assembly of parts</u>

4. Personnel must be carrying out the following tasks;
   4.1. Using a pair of scissors, cut a 300mm length of 18mm wide buttonhole elastic from the roll as shown in the image below:



4.2. Attach one end of the buttonhole elastic to <u>one side</u> of the 3D printed headband component as shown in the image below. The User will attach the other side when putting on the FaceShield to match their head size.



4.3. The assembly process is complete, sign the QC checklist.

Packaging of an individual face shield

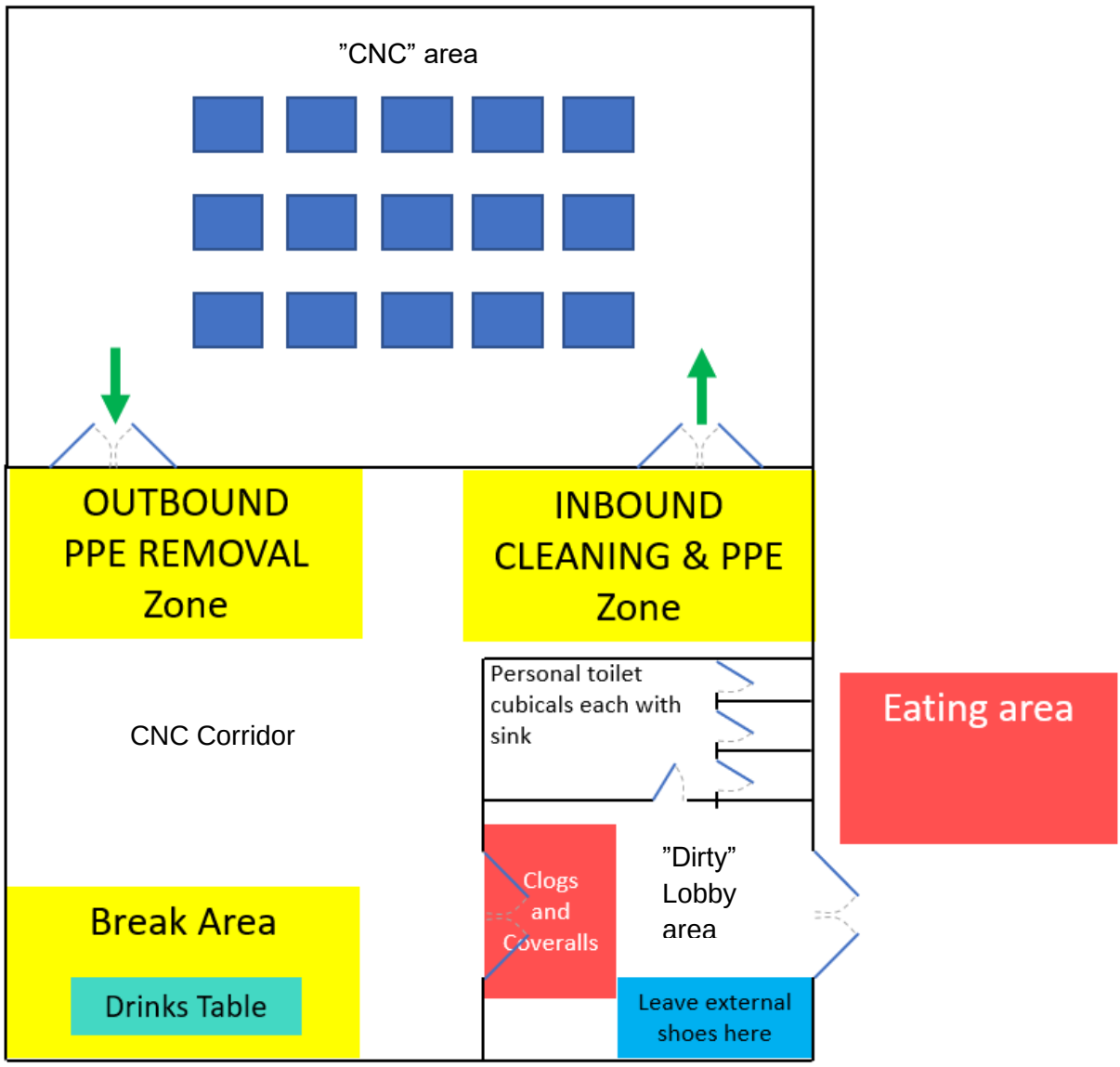
5. Personnel must carry out the following tasks;
   5.1. Open a food grade clear plastic zip lock bag and place in the bag the following:
      5.1.1. Two (2) 3D printed parts and associated elastic
      5.1.2. A 0.5mm thick clear PETG sheets laser cut to specification (see appendix 2 for summary, original source: https://www.prusaprinters.org/prints/25857-prusa-protective-face-shield-rc1)
   5.2. The signed QC checklist
   5.3. Seal the plastic zip lock bag with the QC checklist/label inside as shown (see appendix 4 packaged individual face shield)
   5.4. Place the plastic zip lock bag into a carboard box

Packaging and removal of parts for distribution

6. Personnel must carry out the following tasks;
   6.1. Seal the cardboard box with parcel tape
   6.2. Label the box with batch number and onwards logistics information
   6.3. Pick up the cardboard box and exit the CNC manufacturing area
   6.4. Whilst still wearing PPE, place the cardboard box on the floor in the Outbound PPE area
   6.5. Complete steps 3.3-3.5 of SOP-002 (exiting the CNC manufacturing facility)
   6.6. Take the cardboard box and hand it over to an individual in the dirty side of the lobby area for onward transport

9 APPENDIX

1. Manufacturing Unit Floor plan



2. Summary of 3D printing details from https://www.prusaprinters.org/prints/25857-prusa-protective-face-shield-rc1

PRUSA PRINTERS BETA

Prusa Protective Face Shield - RC3

Prusa Research

VIEW IN BROWSER

updated 27. 3. 2020 | published 26. 3. 2020

Summary

A prototype face shield that we developed. In three days, we went through dozens of prototypes and two verifications with the Czech Ministry of Health.

Check this print for 2 and 4 stack versions.

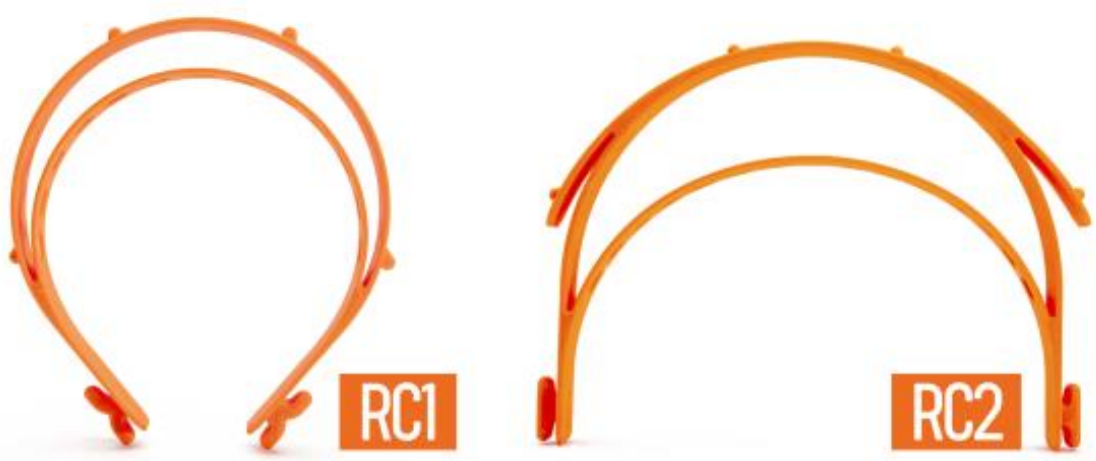
Version RC3 changelog Changes from RC2:

- Removed hexagonal holes for faster printing speeds
  - With faster printing we use on our farm, some pieces had sharp points and based on testing, the venting is not needed as much
- Several optimizations for stack printing
- New print files with 4 headbands stacked on top of each other
  - Stacking headbands is a great idea by the community, especially useful for overnight printing

Version RC2 Changes from RC1:

- Increased wall thickness (slightly stiffer and more durable)
  - Inner wall from 1.5 mm to 2 mm
  - Outer wall from 2 mm to 2.5 mm
- The headband is no longer printed compressed - Lower pressure on the temple
- The visor was moved further away from the forehead - This allows a better fit over bigger respirators and protective goggles
- The printed part now has an extension for the visor (the visor curves less than the headband).

For now, both RC1 and RC2 versions are relevant. RC1 lets you fit more printed parts on a single print bed. However, if maximum yield isn't the priority, RC2 provides slightly better protection and is more comfortable to



Visor / front plate

- there is a DXF drawing in the file section (and an alternative longer version)
- the holes can be made with a standard office hole puncher
- we used 0.5 mm thick petg sheet (Covestro VIVAK), but you should be able to use any clear laser cuttable plastic with similar thickness.

3. Paper sheet printed double sided with important product information, QC checklist and assembly instructions (example below, should be updated for each production location)

Date: -3-20 **Shift:** 6/14/22 **3D Printer:** _____

FACE SHIELD (RC1)

For use with smaller masks

FOR SINGLE USE ONLY – HANDLE WITH CARE

This pack contains the following parts:

- Clear visor
- Headband (fragile) and Elastic Strap
- Lower Support (fragile)

QUALITY CONTROL:

Initials	
	Viability check
	Filament strands removed
	Mechanical flex check headband
	Mechanical flex check lower support
	Nodules force test
	Cut and attach elastic
	Pack with clear visor

DISCLAIMER: This face shield has not been manufactured by a professional medical products manufacturer; it has however been manufactured according to a standard operating procedure that has been developed with voluntary guidance from manufacturing professionals. This face shield is supplied without warranty and has been manufactured as a single use device for use during the COVID-19 pandemic, no liability can therefore be accepted.

Produced at:

Cisco International Limited
300 Longwater Avenue
Reading, RG2 6GE
faceshield@cisco.com

With professional 3D printing guidance led by:

edumaker

Edumaker Ltd.
37 Royal Avenue
Reading, RG31 4UR
@alexgibson3d

ASSEMBLY INSTRUCTIONS OVERLEAF

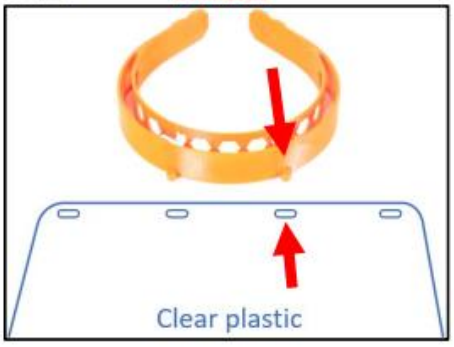
Dear user, thank you for all you do to keep us safe and healthy.

This is a Prusa Protective Face Shield - version RC1/RC2
Designed by the awesome open source 3D printer makers PrusaPrinters.org

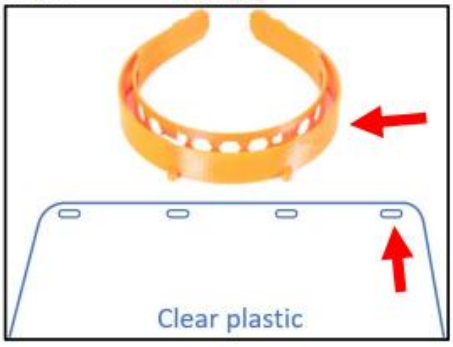
ASSEMBLY INSTRUCTIONS (RC1/RC2/RC3)

For full instructions search "How to assemble the Prusa Face Shield" - These are quick instructions to help with orientation. The assembly order is IMPORTANT.

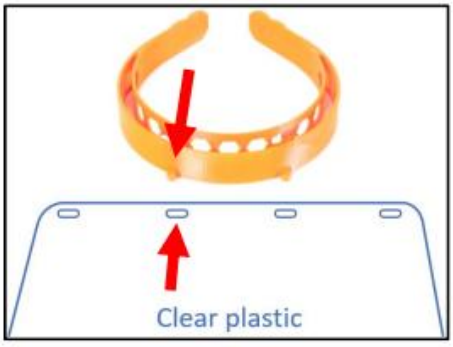
STEP 1 FRAGILE



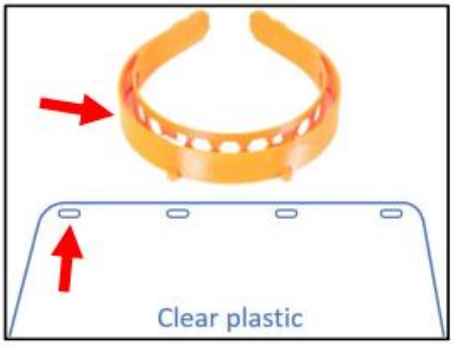
STEP 2 FRAGILE



STEP 3 FRAGILE

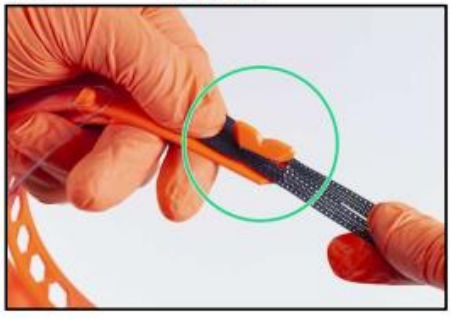


STEP 4 FRAGILE



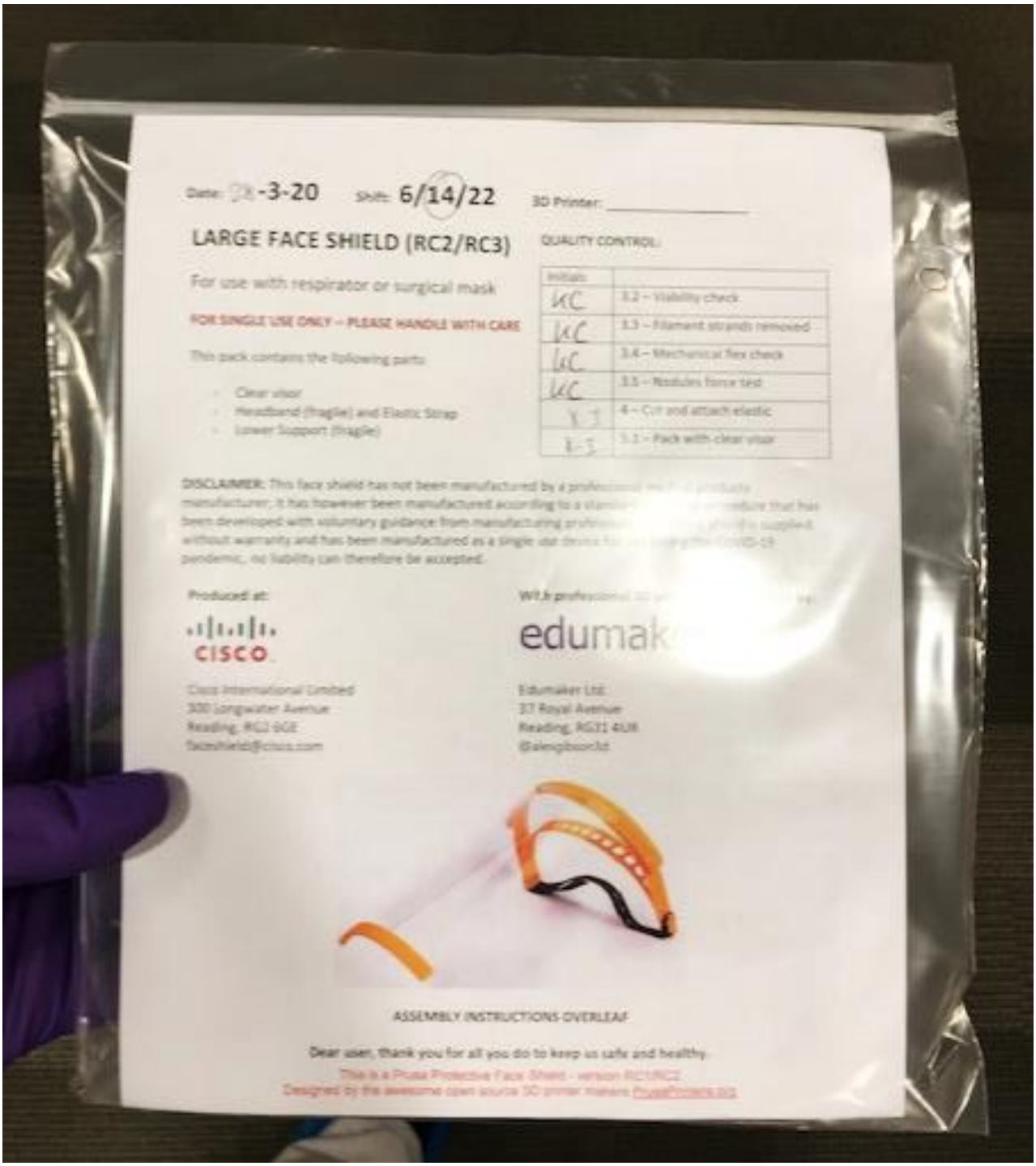
STEP 5 FRAGILE

STEP 6 FRAGILE



This is a Prusa Protective Face Shield - version RC1/RC2
Designed by the awesome open source 3D printer makers PrusaPrinters.org

4. Packaged individual face shield




ASSEMBLY INSTRUCTIONS (RC1/RC2/RC3)
STEP 3
FRAGILE
Clear plastic
FRAGILE
STEP 4
Clear plastic
STEP 6