Biological Evaluation Report on The Smile Shield Transparent Face Mask

Report Prepared by:

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Biological Evaluation Report

a) Strategy and planned content for the biological evaluation of the medical device

The planned strategy was to determine the required testing in relation to the Smile mask. Following a review of the ISO Standard 10993:2018 and EN 14683:2019, it was decided to conduct the following testing:

1. Skin Sensitization
2. Skin Irritation
3. In Vitro Cytotoxicity
4. Bioburden Testing

b) Criteria for determining the acceptability of the material for the Intended Purpose

The criteria for the materials acceptability was determined from a review of relevant standards, based upon the description of the product and its intended purpose identified above.

Manufacturing Facility

The Manufacturing Facility is Anhui Rongda Medical Equipment Co. Ltd., Industrial Park, Renhe Town, Tianchang City 239300, Anhui, China.

In the Production area, all material is tested on a filtration test machine and completed masks are sampled for tensile testing requirements to ISO 14683: 2019+AC:2019. The layers of the mask and the ear loops are sonically welded together. QC Checks are performed by staff, an Inspection and Detection report has been compiled by the Jiangsu Product Quality Testing and Inspection Institute (report number (2020) SJZWJ-WT0824). There is also a Pre-Shipment Inspection report from HQTS, report number H-21060010, that follows ISO 2859 sampling plan.

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Packaging

The Smile Shield packaging is made up of two materials.

Packaging Materials:

Internal Bag - PET

Box - Solid board (Cardboard)

Solid Board Box

PET Bag

Product Description

The Smile Shield mask is a surface contacting medical device that is in contact with in-tact skin surfaces. The mask materials have been taken into consideration when evaluating the biological evaluation of the device. The device is considered by the Manufacturer to be a non-invasive device that contacts only intact skin, and therefore is deemed to be:

Class I Rule I – Either do not touch patient or contact only intact skin

Intended Purpose

This mask is intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.

Instructions For Use (IFU)

The following Instructions For Use (IFU) have been issued. They have also been identified on the outer carton.

1. Wash your hands before touching the mask
2. Hold the mask by the ear loops with the coloured side facing outwards and nose strip upwards.

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3. Place an ear loop over each ear gently without touching the inside surface of the mask.
4. Adjust the nose clip to match the shape of the nose to prevent unfiltered air from entering.
5. Pull the mask pleats below chin to produce a tight seal.

c) Adequacy of the material characterisation

The review of the adequacy of the materials was assessed by means of determining through identified testing, if the materials were adequate for the intended use

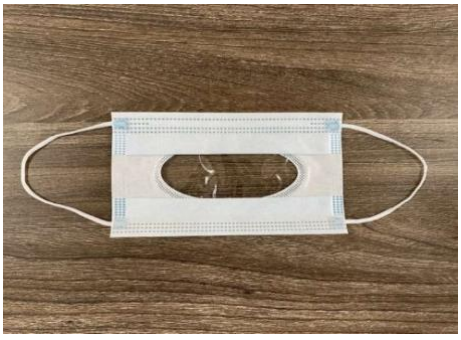
Product Details

The Smile Shield mask is a surface contacting medical device that is in contact with in-tact skin surfaces. The mask materials have been taken into consideration when evaluating the biological evaluation of the device. is made from:

- Inner Layer – Non-woven fabric
- Middle Layer – Non-woven fabric
- Outer Layer – Non-woven fabric
- Clear Panel – CPP (Cast Unoriented Polypropylene)

The device is sold Non-Sterile, with the packaging identifying it as “Single Use Only”.

Front (Outside) of Mask



Rear (Inside) of Mask

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A systematic approach to a biological evaluation of medical devices as part of a risk management process was conducted using the process outlined in annex A. The process identified that a biological evaluation should be performed.

d) Rationale for selection and / or waiving of tests

Following the review of the standard, the applicable tests were determined as those relevant to the process and materials being used.

ISO EN-14683:2019 describes surgical face masks as being skin-contact devices with limited duration of contact. Under current pandemic conditions, the current usage patterns of medical masks mean staff may wear masks for the complete duration of any work shift, which may last up to 13 hours.

The Smile Shield Mask is as a Limited Contact Medical Device (Based on the Biocompatibility Testing Selection Criteria outlined in Annex B).

A framework for the development of an assessment programme was used (Annex B) highlighting three biological evaluation tests were required:

1) Skin Sensitization
2) Skin Irritation
3) In Vitro Cytotoxicity

The results from the test indicate that the materials of the mask are not biologically hazardous, and therefore meet the fitness for purpose criteria as identified in ISO 10993-1:2018. The Test Report is from Jiangsu Science Standard Medical Testing Co. Ltd. With each section individually numbered.

e) Interpretation of existing data and results of testing

A summary of the testing details is given below.

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1. Skin Sensitization Test (ISO 10993-10:2010)

The report is numbered SSMT-R-2020-03682-03A, using masks from Batch RDYL20201221Y.

The test was designed to evaluate the potential of the test sample to cause skin sensitisation using the Guinea Pig maximisation test. The final report was completed on 07Feb21.

The skin sensitization rates of both the polar and non-polar test groups were evidenced at 0%.

The test samples, extracted with 0.9% sodium chloride injection and sesame oil as the negative control, demonstrated no skin reaction either intradermally or following topical application.

The evaluation criteria and results are in sections 9 and 10 of the report respectively. There were no deviations from the SOP that were judged to have any impact on the validity of the data.

2. Skin Irritation Test (ISO 10993-10:2010)

The report is numbered SSMT-R-2020-03682-02A. using masks from Batch RDYL20201221Y.

The animal skin irritation test was conducted to assess the potential irritation of the test article or material. The final report was completed on 07Feb21.

The test sample was extracted with 0.9% sodium chloride injection and sesame oil, respectively. The patches (about 2.5cm x 2.5cm) which moistened by 0.5ml extract of test article were directly applied to the rabbit skin for 4 hours. Observation for erythema and edema were conducted at 1h, 24h, 48h and 72h after removal of the patches.

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The primary irritation indexes of the polar and non-polar test group were both calculated at 0. The test results showed that the extract of the test article did not induce skin irritation in rabbit under the test condition.

3. In Vitro Cytotoxicity Test (ISO 10993-5:2009)

The report is numbered SSMT-R-2020-03682-01A. using masks from Batch RDYL20201221Y.

The study was to investigate the potential cytotoxicity of a mammalian cell culture in response to the test sample. The extract of the test article was added to L-929 cells and then incubated at 37°C in 5% CO_2 for 24 hours. After the incubation, the cell morphology was observed prior to the culture medium being discarded. The results detected with MTT method. The results showed that the cytotoxicity ratio of the 100% test article extract was 82.4% and the results of the control groups showed the test was valid.

Under the conditions of this study, the extract of the test article did not show potential toxicity to L-929 cells.

Bioburden Testing to EN 14683:2019

SGS performed testing on 5 samples from Batch RDY04520200929 as evidenced by Test Report SL52045300037401TX, dated 26Oct2020.

The pre-test performance requirement was identified as ≤30 CFU/g. The test results demonstrated a range from 18.31 to 23.14 CFU/g indicating the samples were within the required specification.

f) The need for any additional data to complete the biological evaluation

The discussion group felt that no further data was required at this stage to complete the evaluation.

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g) Overall biological safety conclusions for the medical device

Following a review of the data provided, the author has identified conclusions below.

Risk Analysis

A risk analysis was conducted to identify the intended use of the device, assess the biological hazards, and conduct an exposure assessment. The risk assessment report is documented in the report SMP-04-00001. There were no potential risks identified with leeching of materials.

The report indicates that the **identified** risks have been mitigated.

The clear panel is made from Cast Unoriented Polypropele (CPP) and has additionally been tested to GB 4806.7-2016 ‘National Food Safety Standard Food Contact Plastic Materials and Products’. CPP material is widely used within skin contact Medical Devices. The material is bonded to the mask using Ultrasonic welding and therefore the risk of the material separating from the mask and causing a choke hazard is extremely low.

In conclusion

The scores evidenced appear to indicate that the risks have been satisfactorily mitigated. The overall indication is that the patient benefits outweigh any residual risks identified.

Further evidence of risk management actions taken include statement 2 on the Cautions and Warnings printed on the box and also the Instructions For Use (IFU) that are also printed on the box.

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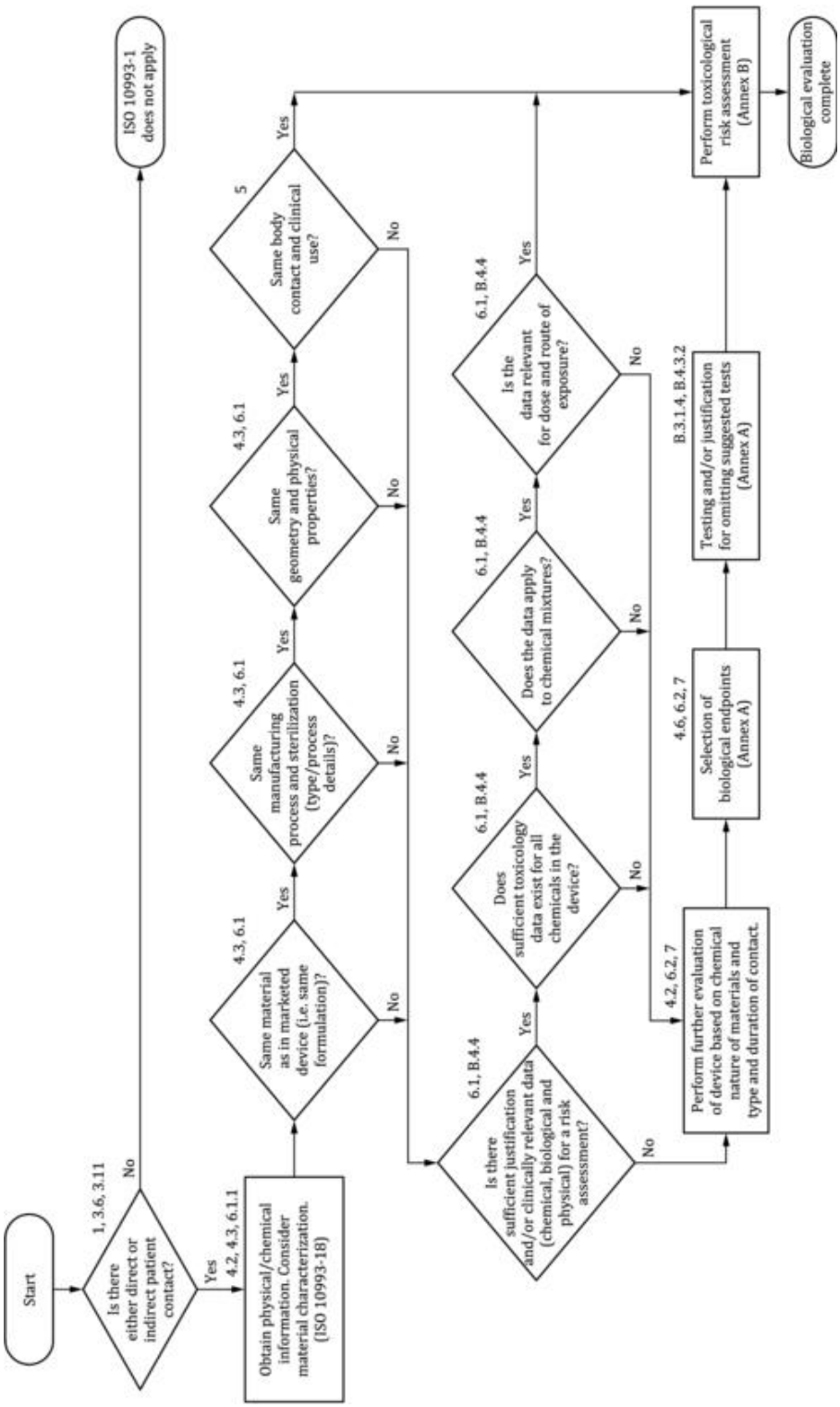
ANNEX A – Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process.



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ANNEX B – Biological Evaluation Tests

Table A.1 is a framework for the development of an assessment programme and is not a checklist (see Clause 6). For particular medical devices, different sets of tests may be necessary, including either more or less testing than is indicated in the Table A.1. In addition to the framework set out in Table A.1, the following should be considered based on a risk assessment, which considers the specific nature and duration of exposure: chronic toxicity, carcinogenicity, biodegradation, toxicokinetics, immunotoxicity, reproductive/developmental toxicity or other organ-specific toxicities.

UL

Testing and Evaluation Strategies for the Biological Evaluation of Medical Devices submitted for CE Mark and FDA Approval

Table 1: ISO 10993-1 Biocompatibility Testing Selection Criteria

Medical device categorization by			Biological Effect [a]							
Nature of body contact		Contact duration								
Category	Contact	A - limited (≤ 24 h) B - prolonged (> 24 h to 30 d) C - permanent (> 30 d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous reactivity	Systemic toxicity (acute)	Subchronic toxicity (subacute toxicity)	Genotoxicity	Implantation	Haemocompatibility
Surface device	Skin	A	X	X	X					
		B	X	X	X					
		C	X	X	X					
	Mucosal membrane	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
	Breached or compromised surface	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
External communicating device	Blood path, indirect	A	X	X	X	X				X
		B	X	X	X	X				X
		C	X	X		X	X	X		X
	Tissue/bone/ dentin	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Circulating blood	A	X	X	X	X				X
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
Implant device	Tissue/bone	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Blood	A	X	X	X	X	X		X	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X

Note:
a The "X" indicates data endpoint that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

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Bibliography

Reference Document	Description
ISO 10993-1:2018	Biological evaluation of medical devices; Part 1 – Evaluation and Testing within a risk management process
ISO 14971:2019	Medical devices – application of risk management to medical devices
Med Dev 2.4.1, rev 9 – Jun2010	Guidelines relating to the classification of medical devices
EN 14683:2019+AC:2019	Medical face masks. Requirements and test methods
ISO 2859-2:2020	Sampling procedures for inspection by attributes
Report (2020) SJZWJ-WT0824	Inspection and Detection report
SSMT-R-2020-03682-01A	In Vitro Cytotoxicity Test
SSMT-R-2020-03682-02A	Skin Irritation Test
SSMT-R-2020-03682-03A	Skin Sensitization Test
Report SL52045300037401TX	SGS Bioburden test Report
SMP-04-00001	Risk Assessment Report
Report H-21060010	HQTS Pre-Shipment Inspection Report
No (2020) SJZWJ-WT0824	GB 4806.7-2016 National Food Safety Standard Food Contact Plastic Materials and Products

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Author

Name	Role	Signature	Date
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The Author has a background of 32 years in Medical Devices and IVDs, with 5 of those years as a Lead Assessor for Notified Bodies including SGS and LRQA, and within these roles, a trained Technical File reviewer. Trained at S&N by Lead Microbiologist in report writing.

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