10A LIMITED
RMS 1001-1005, 10/F, NANYANG PLAZA,57 HUNG TO RD.,KWUN TONG,KLN, HONG KONG

The following sample was submitted and identified by the client as 10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE)

SGS Report No.	:	HKHC2208006001HC (T32220300301SN)
SGS Case No.	:	HKHC220800002554-101 (CA322203017529)
Style/Item No.	:	FM3D-M-LOT-P402
Country of Origin	:	Hong Kong
Country of Destination	:	EU and Hong Kong
Manufacturer	:	10A LIMITED
Labeled Age Grading	:	Adult
Job Receiving Date	:	Aug 16, 2022 – Sep 09, 2022
Report Preparation Period	:	Aug 16, 2022 – Sep 27, 2022

Service Requested
Biological Evaluation of Medical Devices ISO 10993-1:2018 – Biological Evaluation of Medical Devices - Evaluation and testing within a risk management process for said product.

Results
Please refer to the following pages.

Conclusion
Please refer to *Section 8: CONCLUSION*.

Signed for and on behalf of
SGS Hong Kong Ltd.

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European Registered Toxicologist (ERT)
Diplomate American Board of Toxicology (DABT)

1. INTRODUCTION

The product 10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE) by 10A LIMITED is evaluated according to the applicable requirements of ISO 10993-1:2018 – Biological Evaluation of Medical Devices - Evaluation and testing within a risk management process. This ISO10993-1 biological evaluation report has only addressed dermal contact exposure. For the evaluation of inhalation risk, it is indicated that corresponding testing is in progress by the time of assessment and would be attached in the technical file as supplement. The product is for EU and Hong Kong and intended for use by general public as medical face mask.

This biological evaluation is based on the submitted dataset, documents and testing results by the mask manufacturer. It is the responsibility of the manufacturer to provide truthful and valid information that this evaluation based upon. This evaluation took reference of ISO Standards, relevant and existing scientific literature, preclinical and clinical data as well as real-life evidence to determine the product compliance according to ISO 10993-1:2018. The following aspects of the device are considered

a) Medical device configuration (e.g. size, geometry, surface properties) and a listing of a medical device's materials of construction (qualitative) and where necessary, the proportion and amount (mass) of each material in the medical device (quantitative);

b) The physical and chemical characteristics of the various materials of construction and their composition;

c) Any history of clinical use or human exposure data;

d) Any existing toxicology and other biological safety data on product and component materials, breakdown products and metabolites;

e) Test procedures.

2. PRODUCT DETAILS AND INTENDED USE

10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE) is a medical face mask with two head straps for wearing and a nose bridge and nose bar (sponge) for cushion and fitting the face mask around the nose. The mask consisted of 7 components: white spunbond non-woven outer layer, white nanofiber filter layer, white melt-blown middle layer, white spunbond non-woven inner layer, elastic head bands, nose bridge and nose bar. This medical face mask is intended to be worn by adult to protect the general public from the transfer of microorganisms, body fluids, and particulate material. It is a single-use disposable device and provided non-sterile.

Table 1. Product component and manufacturer

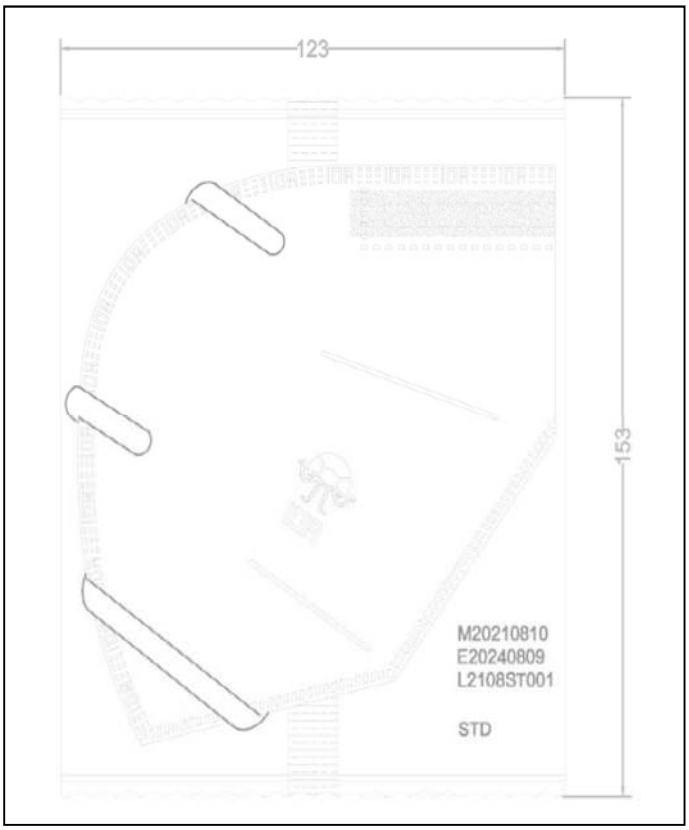
Component	***Material name***	***Composition***	***CAS No.***	***Manufacturer***
Outer layer	*Polyester Spunbond Nonwoven*	*Polyethylene Terephthalate (100%)*	*25038-59-9*	*Wenzhou Yonghong Huaqian Co., Ltd.* *Address: No. 332, Ouhai Avenue, Wenzhou, Zhejiang, 325014 P. R. China* *Tel: +86-577-86763780-8028* *E-mail: lww1638@163.com*

Middle layer	*Melt-Blown*	*Polypropylene (100%)*	*9003-07-0*	*Shanghai Kingfo Industrial Co.,Ltd.* *Address: No.28, Linsheng RD, Tinglin Industrial Area, Jinshan District, Shanghai, China* *Tel: +86-21-37910988-8019* *Fax: +86-21-37910022* *E-mail: 30472943l@qq.com*
Filter layer	*NanoGO™ Nanofiber Non-Woven Fabrics (NanoGO™ PET)*	*Polyethylene Terephthalate (99.4%)* *Polyvinyl Alcohol (0.6%)*	*25038-59-9* *9002-89-5*	*Newtech Textile Technology Development (Shanghai) Co., Ltd.* *Address: 318B, Lianyang Road Songjiang District, Shanghai, China* *Tel: +86-021-57743321*
Inner layer	*PE+PP Bicomponent Nonwovens*	*Polypropylene (50%)* *Polyethylene (50%)*	*9003-07-0* *9002-88-4*	*Shanghai Kingfo Industrial Co.,Ltd.* *Address: No.28, Linsheng RD, Tinglin Industrial Area, Jinshan District, Shanghai, China* *Tel: +86-21-37910988-8019* *Fax: +86-21-37910022* *Email: 30472943l@qq.com*
Ear loop (horizonal head band)	*Ear Loops*	*Nylon (70%)* *Spandex (30%)*	*32131-17-2* *9009-54-5*	*Dongguan Yusen Industrial Co., Ltd.* *Address: No. 48 BingFu road, ShuiBian village, Hengli town, Dongguan City, Guangdong, China* *Tel: +86-13712904008* *E-mail: lindasun@henhenai888.com.cn; hengsen9988@163.com*
Nose bar	*Slow Rebound High Density White Sponge*	*Polyurethane (100%)*	*9009-54-5*	*Dongguan Runfu Polymer Material Co., Ltd.* *Address: No. 3 Office Building, Jujia Science & Technology Park, Runzi Garden Village, Xiegang Town, Donguan City, Guangdong, China* *Tel: +86-15816835545* *E-mail: 402810814@qq.com*
Nose bridge	*Nose Wire*	*Polypropylene (20-30%)* *Galvanized Iron (70-80%)* *Titanium dioxide (0.1-0.2%)*	*9010-79-1* *7439-89-6* *13463-67-7*	*Dongguan Niufa Plastic & Hardware Co., Ltd.* *Address: Chigang Fuma Industrial Zone, Humen, Dongguan, Guangdong, China* *Tel: +86-769-85220148* *Fax: +86-769-85220548* *E-mail: fanbing1583@163.com*

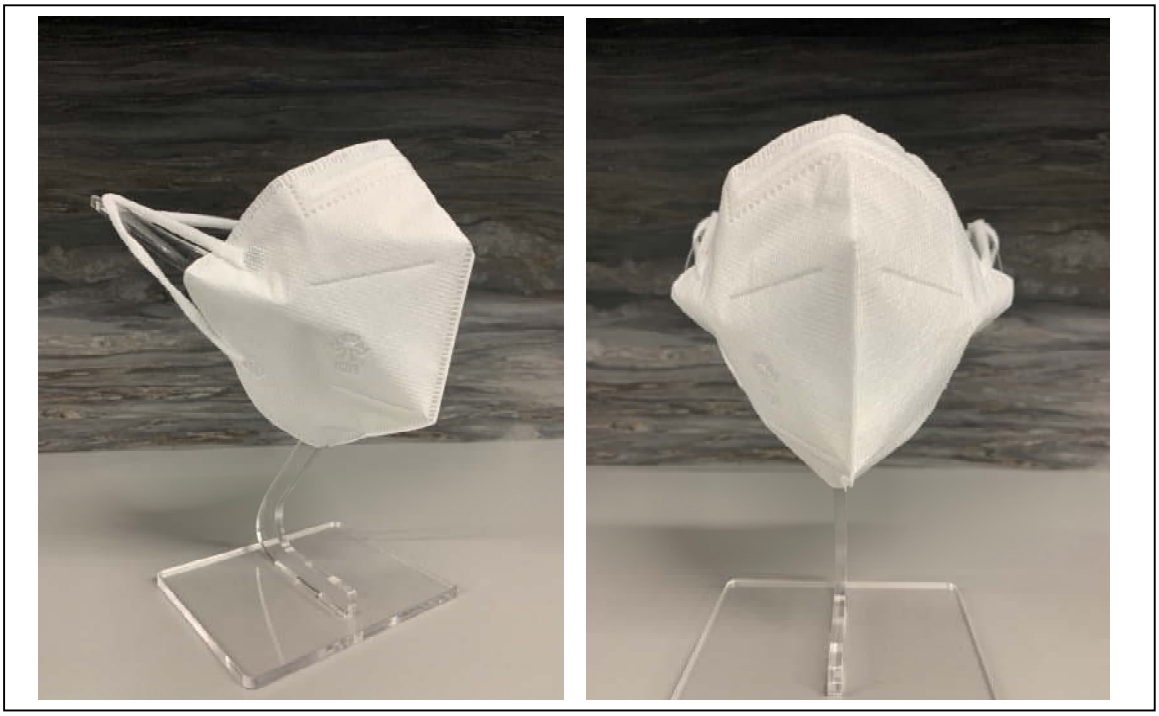
Table 2. Product configuration

	Part description	Diameters (mm x mm)	Weight (g)
1	*Outer layer*	*233 x 126*	*1.671*
2	*Middle layer*	*233 x 126*	*0.840*
3	*Filter layer*	*233 x 126*	*1.137*
4	*Inner layer*	*233 x 126*	*0.981*
5	*Head band (Ear loop)*	*280 (upper), 250 (lower)*	*1.64*
6	*Nose bar*	*100 x 10*	*0.63*
7	*Nose bridge*	*83 x 5*	*0.68*
		Total Weight (g)	*7.58*

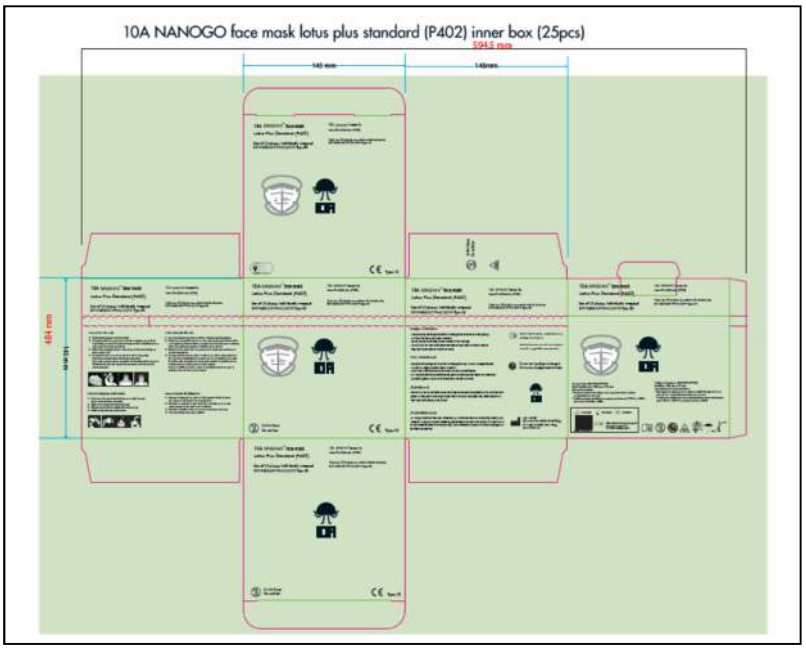
Figure 1. Schematic diagram of face mask



Product photo of the face mask



Product artwork of package



3. BIOLOGICAL ENDPOINTS NEEDED TO BE CONSIDERED

10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE) is intended for general protection and being used continuously for no more than 8 hours. It is hence considered as surface medical device with limited contact (< 24 h) with intact skin according to ISO 10993-1:2018 based on the nature and contact duration with intended use (Table 3). Biological endpoints of cytotoxicity, sensitization and irritation or intracutaneous reactivity of the final product should be evaluated for the biological risk assessment either through the use of existing data, endpoint-specific testing, or a rationale to justify why assessment of the endpoint does not required.

Components	***Physical contact***	***Contact area***	***Contact duration***
Outer layer	*No direct contact*	*N/A*	*N/A*
Middle layer	*No direct contact*	*N/A*	*N/A*
Filter layer	*No direct contact*	*N/A*	*N/A*
Inner layer	*Direct contact*	*Intact skin (face and neck)*	*< 24 h*
Nose bridge	*No direct contact*	*N/A*	*N/A*
Nose bar	*Direct contact*	*Intact skin (area around nose and face)*	*< 24 h*
Head band	*Direct contact*	*Intact skin (area around head and neck)*	*< 24 h*

Table 3. Endpoints to be addressed in a biological risk assessment

Medical device categorization by			***Endpoints of biological evaluation***													
Nature of body contact		***Contact duration***	*Physical and/or chemical information*	*Cytotoxicity*		*Irritation or intracutaneous reactivity*	*Material mediated pyrogenicity*	*Acute Systemic toxicity*	*Subacute toxicity*	*Subchronic toxicity*	*Chronic toxicity*	*Implantation effects*	*Hemocompatibility*	*Genotoxicity*	*Carcinogenicity*
Category	***Contact***	***A- limited*** (≤ 24h) ***B- prolonged*** (>24h to 30 d) ***C- long term*** (>30d)														
Surface medical device	*Intact skin*	*A*	*X*	*E*	*E*	*E*										
		B	*X*	*E*	*E*	*E*										
		C	*X*	*E*	*E*	*E*										
	Mucosal membrane	*A*	*X*	*E*	*E*	*E*										
		B	*X*	*E*	*E*	*E*		*E*	*E*			*E*				
		C	*X*	*E*	*E*	*E*		*E*	*E*	*E*	*E*	*E*		*E*		
	Breached or compromised surface	*A*	*X*	*E*	*E*	*E*	*E*	*E*								
		B	*X*	*E*	*E*	*E*	*E*	*E*	*E*			*E*				
		C	*X*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*		*E*	*E*	
Externally communicating medical device	*Blood path, indirect*	*A*	*X*	*E*	*E*	*E*	*E*	*E*					*E*			
		B	*X*	*E*	*E*	*E*	*E*	*E*	*E*				*E*			
		C	*X*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	
	Tissue/ bone/ dentin	*A*	*X*	*E*	*E*	*E*	*E*	*E*								
		B	*X*	*E*	*E*	*E*	*E*	*E*	*E*			*E*		*E*		
		C	*X*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*		*E*	*E*	
	Circulating blood	*A*	*X*	*E*	*E*	*E*	*E*	*E*					*E*	*E*		
		B	*X*	*E*	*E*	*E*	*E*	*E*	*E*			*E*	*E*	*E*		
		C	*X*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	*E*	

4. PHYSICAL AND CHEMICAL CHARACTERIZATION OF CONSTITUENT AND MATERIAL

The physical and chemical characterisation of constituents present in the mask components is summarized in Table 4. Components with direct contact with the intact skin is of more concern. The Material Safety Data Sheet (MSDS), Certificate of Analysis (COA) of the ingredients and supporting documents on the chemical purity of the components has been requested, whenever possible, to demonstrate the chemical purity of the raw materials and is summarized in Table 6.

Table 4. Toxicological/ Chemical profile of constituents

Chemical Name	***CAS No.***	***Materials***	***Direct contact with skin***	***Toxicological profile***
Polypropylene	*9003-07-0*	*Middle layer* *Inner layer* *Nose bridge*	*No* *Yes* *No*	*Polypropylene (PP), also known as polypropene, is a thermoplastic polymer used in a wide variety of applications. It is produced via chain-growth polymerization from the monomer propylene. PP belongs to the group of polyolefins and is partially crystalline and non-polar. Its properties are similar to polyethylene, but it is slightly harder and more heat resistant. It is a white, mechanically rugged material and has a high chemical resistance. PP is available as molding powder, extruded sheet, cast film, textile staple or continuous filament yarn. Manufactured products include packaging film, wire and cable coatings, food containers, plastic pipe, wearing apparel, and reinforced plastics; also molded parts for automobiles, appliances, and houseware. IARC determined that PP is not classifiable as to its carcinogenicity to humans (Group 3) based on no adequate human data and inadequate animal data.*
Polyethylene	*9002-88-4*	*Inner layer*	*Yes*	*Polyethylene (PE) is a polymer of ethylene monomers. It can be branched or linear. Branched or low-density polyethylene (LDPE) is tough and pliable but not to the same degree as linear polyethylene. Linear or high-density polyethylene has a greater hardness and tensile strength. PE is used in a variety of medical devices including implants and prostheses.*
Polyethylene Terephthalate	*25038-59-9*	*Filter layer* *Outer layer*	*No* *No*	*Polyethylene Terephthalate (PET) formed from terephthalic acid or its esters and ethylene glycol. It can be formed into tapes, films or pulled into fibres that are pressed into meshes or woven into fabrics. PET is not considered an orthophthalate nor require the use of phthalates or other softening additives, therefore, there is low concern regarding estrogenic activity of PET. It is a large polymer with no chemical reactivity on its surface, and this long-chain polymer would not penetrate the skin. Based on the chemical and biological properties of this ingredient, deposition in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns while incidental inhalation would not be a significant route of exposure that is unlikely to lead to local respiratory or systemic effects. PET used in medical devices was not considered to pose a significant risk due to its inert nature.*
Polyvinyl Alcohol	*9002-89-5*	*Filter layer*	*No*	*Polyvinyl Alcohol (PVA) is the synthetic alcohol polymer with typical molecular weights ranged from 25,000 to 300,000. It is approved for use as an indirect food additive as well as*

				cosmetic. The polyvinyl alcohol may contain trace amounts of acetaldehyde as an impurity. PVA is only minimally absorbed following oral administration and possesses a low order of acute oral toxicity. The acute oral LD50 in rats is reported to be greater than 10g /kg. There was no evidence of toxicity in either the 90-day or 2- generation studies at the highest dose levels tested of 5000 mg/kg bw/day. PVA is neither mutagenic nor genotoxic. There is no evidence to indicate that PVA has carcinogenic activity. PVA was not an ocular irritant in animal or clinical studies, nor was it a sensitizer. Some evidence of dermal irritation in animal and clinical studies was seen, but in the clinical studies it was not considered clinically significant. Controlled human studies are limited, but there is a history of use of PVA for several different applications. In particular, PVA is commonly used in film coating formulations for pharmaceutical tablets and capsules in Europe, Japan, and the United States. There is no evidence that such use has resulted in any adverse effects in humans.
Nylon	*32131-17-2*	*Head band*	*Yes*	*Nylon-66 is a polyamide formed by the reaction of adipic acid with hexylenediamine. Nylon-66 can be used primarily as bulking, opacifying, and film forming agents in consumer products. According to CIR, is monomer, adipic acid, was not carcinogenic in a 2-year study in rats fed diets containing up to 5% adipic acid. There is lack of systemic toxicity at high doses in several acute and subchronic oral exposure studies, little or no irritation or sensitization in multiple tests of dermal and ocular exposure, absence of genotoxicity in multiple Ames test, and lack of carcinogenicity in a lifetime oral exposure study. The size of the polymers would limit significant dermal penetration but residual monomer could be absorbed dermally. However, residual monomer would not be present at a sufficient level to cause any biological reaction in any subjects, as supported by test data of another Nylon polymer (Nylon-12) with its maximum concentration of 35% showing no irritation or sensitization.*
Spandex	*9009-54-5*	*Head band*	*Yes*	*Spandex is an elastomeric fibre that has a superior elasticity. It is commonly used for making various textiles such as sportswear, tights and leggings. It is consisted of a chain like arrangements of soft stretchable segments of polyurethane linked together for reinforcement by hard segment.*
Polyurethane	*9009-54-5*	*Nose bar*	*Yes*	*Flexible polyurethane foams are made using toluene diisocyanate (80% 2,4-isomer, 20% 2,6-isomer), polyfunctional polyols, blowing agents, catalysts and surfactants. Rigid polyurethane foams are typically the reaction products of polymethylene polyphenyl isocyanate with polyether polyols,*

				typically where the polyols are preblended with the surfactants and catalysts as one package and the isocyanate comprises the other component. Polyurethane foam is widely used foam insulation. It has been classified as category 3 by IARC. The inhalation TCLo for human is 12mg/m3 with visual field change to eyes. Provided the ingredient is well-cured with technically unavoidable monomers, it is not expected to raise a particular health concern when used in consumer product.
Iron	*7439-89-6*	*Nose bridge*	*No*	*Iron is the element consisting of metallic iron. It is practically non-toxic. The oral LD50 was found to be 98.6 ± 26.7 g/kg bw. Reduced iron is of very low toxicity based on the LD50 in males. It is neither a skin and eye irritant nor a skin sensitizer. Iron is not genotoxic with animal studies.*
Titanium Diioxide	*13463-67-7*	*Nose bridge*	*No*	*Titanium dioxide (CI 77891) is the inorganic oxide with an empirical formula TiO2. It functions as opacifier, UV absorber, UV filter and colorant in cosmetics as well as other consumer product. INCI name CI 77891 should be used when it functions as colorant. CI 77891 is generally used as white colorant and allowed in cosmetic products according to EU Cosmetic Regulation and should fulfill the purity criteria as set out in Commission Directive 2008/128/EC (E171). IARC concluded that there is inadequate evidence in humans for the carcinogenicity of titanium dioxide but sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. On Jun 9, 2017, the ECHA's Committee for Risk Assessment (RAC) assessed the carcinogenic potential of titanium dioxide against the criteria in the EU Classification, Labelling and Packaging (CLP) Regulation and, having considered the available scientific data, concluded that it meets the criteria to be classified as suspected of causing cancer (category 2, through the inhalation route) (ECHA/PR/17/10). The committee also concluded that there was insufficient evidence to classify titanium dioxide in the more severe category for carcinogenicity (category 1B) as was originally proposed by the French Agency for Food, Environmental and Occupational Health and Safety. For US FDA, titanium dioxide may used as a color additive in contact lenses and intraocular lens orientation marks in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect and shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).*

5. MANUFACTURING PROCESS AND STERILIZATION

5.1 Manufacturing of components

Figure 2. Schematic diagram of manufacturing procedures as provided by the manufacturer

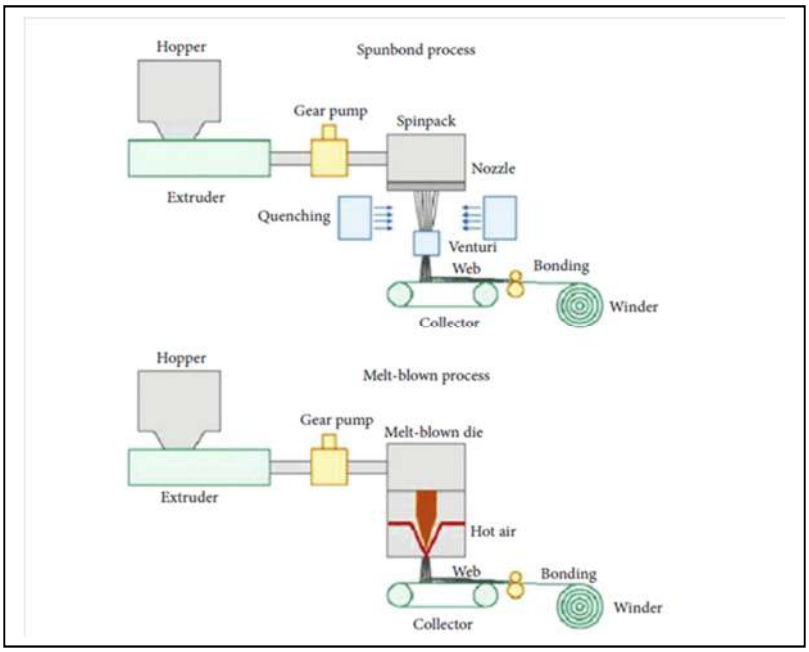


Table 5. Manufacturing process of components of 10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE) as provided by the manufacturer

No	*Component*		*Chemical Constituent*	*Production Process/Technology*
1	*Mask main body*	*Outer layer*	*Polyethylene Terephthalate*	*Spunbond-typed polymer extrusion technology to produce spunbond non-woven PP fabric (refer to Figure 2. Spunbond process).*
		Filter layer	*Polyethylene Terephthalate, Polyvinyl alcohol*	*The PET spunbond nonwoven with nanofiber layer is produced by a modified spunbond machine (refer to Figure 2. Spunbond process). The PET nonwoven is produced by the conventional spunbond spinning method. Nanofibers are generated in a high-voltage electrostatic field from the polymer solution (Polyvinyl alcohol) in the generator and collected into a nanofiber layer on the PET nonwoven on the rotated collector. The PET spunbond nonwoven with nanofiber is manufactured.*
		Middle layer	*Polypropylene*	*Meltblown-typed polymer extrusion technology to produce meltblown non-woven PP fabric (refer to Figure 2. Melt-blown process) under hot air assistant which flow toward the collector and are cooled to form a web.*

		Inner layer	*Polypropylene, Polyethylene*	*Spunbond-typed polymer extrusion technology to produce spunbond non-woven PP fabric (refer to Figure 2. Spunbond process).*
2	*Head band*		*Nylon, Spandex*	*Conversion of spandex and nylon masterbatches into fine and elastic threads.*
3	*Nose bar*		*Polyurethane*	*Raw material react to form polyurethane foam and cut to suitable size.*
4	*Nose bridge*		*Polypropylene, Iron, Titanium dioxide,*	*Wrapping of two iron wires within a plastic PE coating.*

Table 5 show the chemical constituents of the component and it is indicated by the manufacturer that no additives (antioxidants, UV stabilizers, dyes etc.) and processing aids (solvents, lubricants, antifoaming agents, etc.) have been added during the manufacturing process of the components.

5.2 Manufacturing of Mask

The workflow of manufacturing 10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE) is indicated by the manufacturer as follow:

1. Inspection of raw materials and machines for each production process is conducted to ensure the production line and raw materials are in order and quality acceptable based on standard.

2. Material (4 layers non-woven fabrics, nose wire and head bands) are place and fixed on each machine module and stacked in the correct order for lamination.

3. Fabrics are assembled and welded into one, while nose wire and head band is continuously passing through the laminator and is attached into the laminated 4-layer non-woven fabric.

4. Semi product inspection is performed by QC personnel to ensure all parts are welded together. Substandard product is being separated.

5. Final product inspections performed by QC personnel to ensure product conformity. All raw materials, semi-finished product and final product are well-documented under QA management. There are no sterilization procedure and the final product is regard as non-sterile product.

The manufacturing setting, 10A LIMITED, was certified according to ISO 13485:2016 for the Design and Development, Manufacture of non-sterile disposable medical face masks by third party certification organization (bsi Certificate No. MD 753045 with validity till 2024-12-02). The product is expected to be manufactured under QMS for quality assurance.

6. SUBMITTED DATASET FOR THE EVALUATION

The submitted dataset and document by the manufacturer of the mask, 10A LIMITED, in supporting to this biological evaluation of 10A NANOGO FACE MASK LOTUS PLUS P402 COLOR: WHITE (NATURE) is summarized in Table 6. These proprietary documents and reports in electronic version are not presented in

this report in detailed, whereas they are recorded in the SGS Archives. Prior written authorization by the manufacturer is required in case of information requested by regulatory authorities or any other stakeholders.

Table 6. Submitted dataset and document by the manufacturer

Category	Subcategory	Document description	File name (Report No.)
Materials	Outer layer	Material MSDS	PET MSDS-1.JPG, PET MSDS-2.JPG, PET MSDS-3.JPG, PET MSDS-4.JPG,
		ISO 10993-5 test report	1-Outer Layer PET 50gsm Nonwoven 10993-5 ENG.pdf Report No.: SSMT-R-2021-01802-01B Sample: 50gsm PET Non-woven Testing period: 2021-05-28-2021-06-10 Result: Did not show potential toxicity under testing condition
		ISO 10993-10 test report- skin irritation	5-Outer Layer PET 50gsm Nonwoven 10993-10 SI ENG.PDF Report No.: SSMT-R-2021-01974-01B Sample: 50gsm PET Non-woven Testing period: 2021-06-10- 2021-08-09 Result: Did not induce skin irritation under the test condition
		ISO 10993-10 test report- skin sensitization	5-Outer Layer PET 50gsm Nonwoven 10993-10 SS ENG.PDF (Report No.: SSMT-R-2021-01974-02B Sample: 50gsm PET Non-woven Testing period: 2021-06-10 - 2021-08-09 Result: Skin sensitization was not determined
	Middle layer	Material MSDS	4-Middle Layer-MB SDS.pdf
		ISO 10993-5 test report	2-Filter Layer MB 25gsm Nonwoven ENG.pdf Report No.: SSMT-R-2021-00348-01B Sample: 25gsm Melt-blown Non-woven Testing period: 2021-02-01-2021-02-05 Result: Did not show potential toxicity under testing condition
	Filter layer	Material MSDS	5-Filter Layer NanoGO SDS For PET Nano-fiber Non-woven.pdf
		ISO 10993-5 test report	3-Nanofiber PET 30gsm Nonwoven ENG.pdf Report No.: SSMT-R-2021-00351-01B Sample: 30gsm PET Nanofiber Non-woven Testing period: 2021-02-01- 2021-02-05 Result: Did not show potential toxicity under testing condition
	Inner layer	Material MSDS	3-Inner Layer-EP SDS.pdf
		ISO 10993-5 test report	4-Inner Layer EP 25gsm Nonwoven 10993-5 ENG.pdf Report No.: SSMT-R-2021-00350-01B Sample: 25gsm EP Non-woven Testing period: 2021-02-01- 2021-02-05 Result: Did not show potential toxicity under testing condition
		ISO 10993-10 test report- skin irritation	1-Inner Layer EP 25gsm Nonwoven 10993-10 SI ENG.PDF

			Report No.: SSMT-R-2021-01973-01B *Sample: 25gsm EP Non-woven* *Testing period: 2021-06-10- 2021-08-09* *Result: Did not induce skin irritation under the test condition*
		ISO 10993-10 test report- skin sensitization	*1-Inner Layer EP 25gsm Nonwoven 10993-10 SS ENG.PDF* *Report No.: SSMT-R-2021-01973-02B* *Sample: 25gsm EP Non-woven* *Testing period: 2021-06-10-2021-08-09* *Result: Skin sensitization was not determined*
	Head band	*Material MSDS*	*2-Earloop-EL-MSDS-3-7mm-20210409.pdf*
		ISO 10993-10 test report- skin irritation	*4-Ear Loop-SSMT-R-2021-01981-02A-ISO 10993-10 Skin Irritation Test-ear loop-210709.pdf* *Report No.: SSMT-R-2021-01981-02A* *Sample: low pressure ear loop/ head band* *Testing period: 2021-06-10 - 2021-07-09* *Result: Did not induce skin irritation under the test condition*
		ISO 10993-10 test report- skin sensitization	*4-Ear Loop-SSMT-R-2021-01981-03A-ISO 10993-10 Skin Sensitization Test-ear loop-210719.pdf* *Report No.: SSMT-R-2021-01981-03A* *Sample: low pressure ear loop/ head band* *Testing period: 2021-06-10 - 2021-07-09* *Result: Skin sensitization was not determined*
	Nose bar	*Material MSDS*	*1-Nose Bar-NS-MSDS-EN-20210618.pdf*
		ISO 10993-5 test report	*5-Nose Bar-TR-ISO10993-5, wh nose sponges-SSMT-R-2022-02259-01B.pdf* *Report No.: SSMT -R-2022-02259-01B* *Sample: slow rebound nose bar/sponge/cushion foam* *Testing period: 2022-05-05- 2022-06-09* *Result: Did not show potential toxicity under testing condition*
		ISO 10993-10 test report- skin irritation	*2-TR-ISO10993-10, wh nose sponges-SSMT-R-2022-02259-02B ENG.pdf* *Report No.: SSMT-R-2022-02259-02B* *Sample: slow rebound nose bar/ sponge/ cushion foam* *Testing period: 2022-05-05-2022-06-01* *Result: Did not induce skin irritation under test condition*
		ISO 10993-10 test report- skin sensitization	*3-TR-ISO10993-10, wh nose sponges-SSMT-R-2022-02259-03B ENG.pdf* *Report No.: SSMT-R-2022-02259-03B* *Sample: slow rebound nose bar/ sponge/ cushion foam* *Testing period: 2022-05-05 - 2022-06-14* *Result: Skin sensitization was not determined*
	Nose bridge	*Material MSDS*	*6-Nose wire material safety data sheets(MSDS).pdf; 6-双芯鼻梁条 5.0 0.7 物质安全表(MSDS).pdf*

	Whole mask	*ISO 10993-5 test report*	*6-Whole Mask-SSMT-R-2021-01994-01A Amd01-ISO 10993-5 In Vitro Cytotoxicity Test-mask-210719.pdf* *Report No.: SSMT-R-2021-01994-01A Amd01* *Sample: Mask* *Testing period: 2021-06-15-2021-07-19* *Result: Did not show potential toxicity under testing condition*
Production	*Nonwoven*	*Production workflow*	*brief introduction of spunbond-electrospinning.docx; Inner Layer; Outer Layer; Meltblown 1; Meltblown 2;*
	Filter layer	*Production workflow*	*brief introduction of spunbond-electrospinning.docx;* *NanoGO 普通纳米纤维介绍.docx*
	Nose bar	*Production workflow*	*brief introduction of spunbond-electrospinning.docx*
	Nose bridge	*Production workflow*	*brief introduction of spunbond-electrospinning.docx*
	Finished product	*Assembly / production of finished product*	*brief introduction of spunbond-electrospinning.docx*
Product	*N/A*	*Dimension and weight of components*	*Info sheet-biocompatibility P402-v0906.docx; email correspondence*
		Product photo.	*P402.jpg, P402-2.jpg*
		Package photo.	*BACK-03.png, BOTTOM-06.png, FRONT-05.png, LEFT-02.png, RIGHT-01.png, TOP-04.png, BOX_P402_CE MDR_220629.pdf*
Test Reports	*N/A*	*Microbial cleanliness / Bioburden test report*	*[Lotus Plus V2-P402-EN 14683]T32120290343SN.pdf* *(Report No.: T32120290343SN)*
		Bacterial filtration efficiency (BFE) test report	*[Lotus Plus V2-P402-EN 14683]T32120290343SN.pdf* *(Report No.: T32120290343SN)*
		Particulate filtration efficiency (PFE) test report	*[Lotus Plus V2-P402-EN 149] SL12100295804101TX.pdf* *(Report No.: SL52115295849201TX)*
		Differential pressure/ Breathability test report	*[Lotus Plus V2-P402-EN 14683]T32120290343SN.PDF* *(Report No.: T32120290343SN) /* *[Lotus Plus V2-P402-EN 149] SL12100295804101TX.pdf* *(Report No.: SL52115295849201TX)*
		Resistance to penetration by synthetic blood/ Splash resistance test report	*[Lotus Plus V2-P402-EN 14683]T32120290343SN.pdf* *(Report No.: T32120290343SN)*
		Flammability test report	*[Lotus Plus V2-P402-EN 149] SL12100295804101TX.pdf* *(Report No.: SL52115295849201TX)*
Miscellaneous	*Certification*	*ISO 13485 Certificate*	*[10A Limited-ISO 13485](2021-12-03) MD 753045 (2024-12-02)* *(Certificate No. MD 753045)*

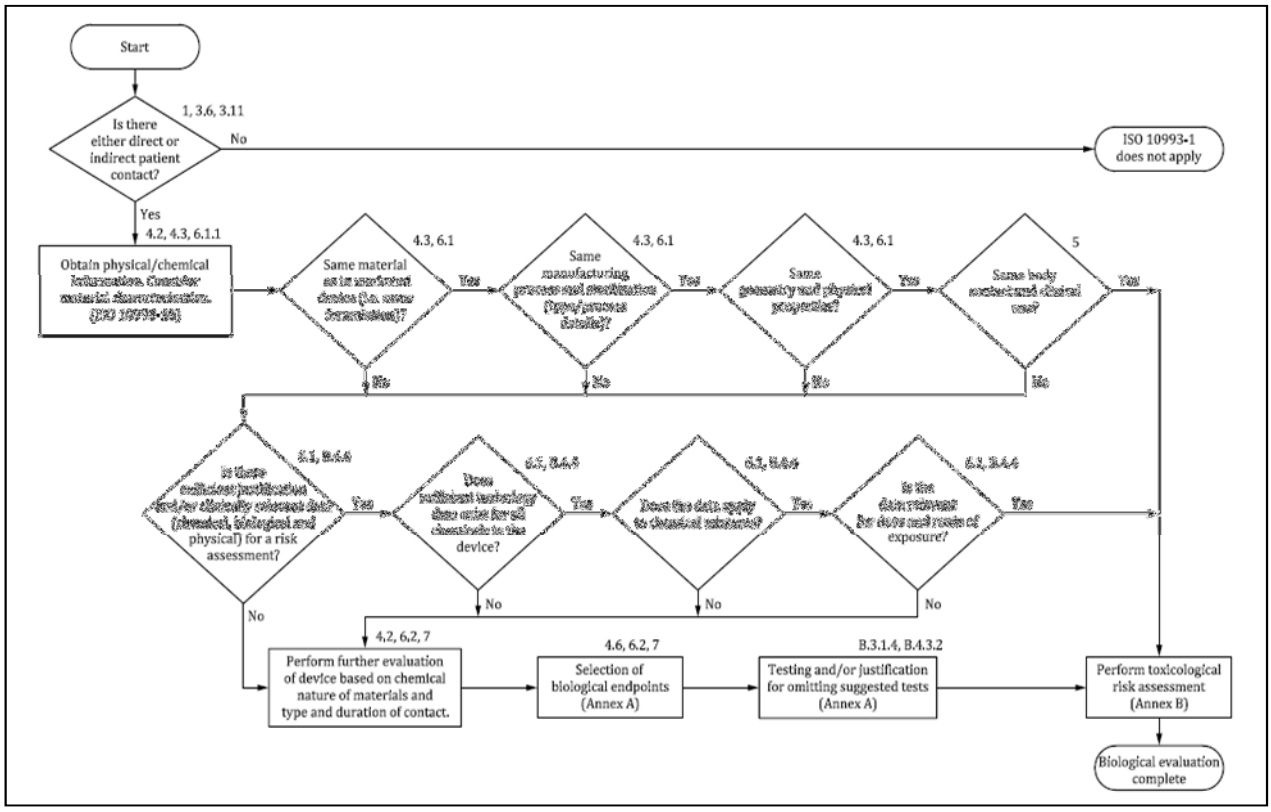
7. AVAILABILITY AND GAP ANALYSIS FOR BIOLOGICAL ENDPOINTS

For the biological risk assessment, compliance with applicable and relevant biological endpoints, based on the surface device and contact intact skin for limited contact duration, is addressed and summarized as following.

Table 7. Evaluation of Biological Endpoints

Biological endpoints	***Available dataset***	***Testing result or justification for exemption***
Material Characterization	*Raw material MSDS on outer layer, middle layer, filter layer, inner layer, head band, nose bar and nose bridge*	• *Only the inner layer, head band and nose bar directly contact with the intact skin.* • *The inner layer is composed of 50% of polypropylene and 50% of polyethylene.* • *The nose bar is indicated to be consisted of 100% of polyurethane.* • *The head band is consisted of 70% of nylon and 30% of spandex.* • *The substances are either stable or inert materials that is well-received in the market with a long history of use for surgical face mask.* • *There is no additive added and sterilization during the manufacturing process and hence issue of residual solvent, degradation and by-product is not expected.* • *The manufacturing setting is certified with ISO13485 to ensure QMS is in place.*
Cytotoxicity	*ISO 10993-5 test report on outer layer, inner layer, middle layer, filter layer, nose bar and whole mask*	• *All the tested samples indicated a negative cytotoxicity result.* • *Only the inner layer, head band and nose bar directly contact with the intact skin.* • *No cytotoxicity test has been performed on head band* • *The head band is consisted of nylon and spandex and has been well-received in the market.*
Irritation or intracutaneous reactivity	*ISO 10993-10 Skin irritation test report on outer layer, inner layer, head band and nose bar*	• *Only the inner layer, head band and nose bar directly contact with the intact skin.* • *All the tested samples indicate a negative skin irritation result.* • *The tested samples are not expected to raise a concern of skin irritation when used as intended.*
Sensitization	*ISO 10993-10 Skin sensitization test report on outer layer, inner layer, head band and nose bar*	• *Only the inner layer, head band and nose bar directly contact with the intact skin.* • *All the tested samples indicate a negative skin sensitization result.* • *The samples are not expected to raise a concern of skin sensitization when used as intended.*

Figure 3. Summary of the Systematic Approach to this Biological Evaluation According to ISO 10993-1: 2018



Based on the submitted information from the manufacturer, the components (outer layer, middle layer, inner layer, head band, nose bar and nose bridge) of the device under assessment are indicated to be of same / similar materials as in the marketed device, of similar manufacturing process and sterilization process, of similar geometry and physical properties and with same body contact and use. The filter layer of the device is sandwiched between the outer layer and the middle layer/inner layer, so it would not directly contact with intact skin when used as intended, resulting in negligible dermal exposure.

8. CONCLUSION

The evaluated device is a classified surface device and contact intact skin for limited contact duration. The submitted documents and dataset permit an evaluation with ISO 10993-1 regarding to relevant biological endpoints. Based on the submitted dataset by the manufacturer and existing scientific data, it is concluded that, in the present state of knowledge, the device would not expected to pose a significant risk in intended users when used as instructed by dermal contact.

The Biological Evaluation is conducted under the following conditions:

1. This biological evaluation is based on the submitted dataset, documents and testing results by the mask manufacturer. It is the responsibility of the manufacturer to provide truthful and valid information that this evaluation based upon.
2. The biological evaluation also taken into account available preclinical tests, clinical investigations, post-market
   experience from similar medical devices or materials, and other relevant information.
3. The biological risk assessment of materials or final products shall be re-evaluated if any of the following occur:
   a) any change in the source or in the specification of the materials used in the manufacture of the product;
   b) any change in the formulation, processing, primary packaging or sterilization of the product;
   c) any change in the manufacturer's instructions or expectations concerning storage;
   d) any change in the intended use of the product;
   e) any evidence that the product can produce adverse biological effects when used in humans.

The validity of this review depends on accurate disclosure by both the manufacturer(s) of the components and of the finished products. Best professional capabilities are used in performing this review. If client wishes to use this opinion with any alterations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. A review of this assessment should be programmed at regular and frequent intervals (upon reformulation of the components or the finished products or upon any change to health and safety regulations).

******** End of Report ********