L&T INTERNATIONAL GROUP, PHILIPPINES, INC.
7500 A. BONIFACIO AVE. COR.J. TINSAY ST.
CLARK FREEPORT ZONE, ANGELES
2009 PAMPANGA, PHILIPPINES

The following sample / information of the product was submitted and identified by the client as RB PRO SURGICAL RESPIRATOR

SGS Report No.	:	HKHC2203001823HC (T32220250435SN)
SGS Case No.	:	HKHC220300000895-101 (CA322202525449)
Style/Item No.	:	FM3D-M-RBF-PB401
Country of Origin	:	Philippines
Country of Destination	:	Philippines, Hong Kong
Manufacturer	:	L&T International Group Philippines, Inc.
Labeled Age Grading	:	Adult
Job Receiving Date	:	Mar 22, 2022 – Aug 16, 2022
Report Preparation Period	:	Mar 22, 2022 – Aug 17, 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.

Mei-Yin CHIU, Sondy
MPH, MSc, FRSB, FRSPH, CBiol
European Registered Toxicologist (ERT)
Diplomate American Board of Toxicology (DABT)

1. INTRODUCTION

The product RB PRO SURGICAL RESPIRATOR by L&T International Group Philippines, Inc. 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 Philippines 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

RB PRO SURGICAL RESPIRATOR is a medical face mask with ear loop for wearing and a nose bridge and nose bar for fitting the face mask around the nose. The mask consisted of 7 components: white spunbond non-woven outer layer, white melt-blown middle layer, white filter layer, white spunbond non-woven inner layer, elastic ear loops, 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

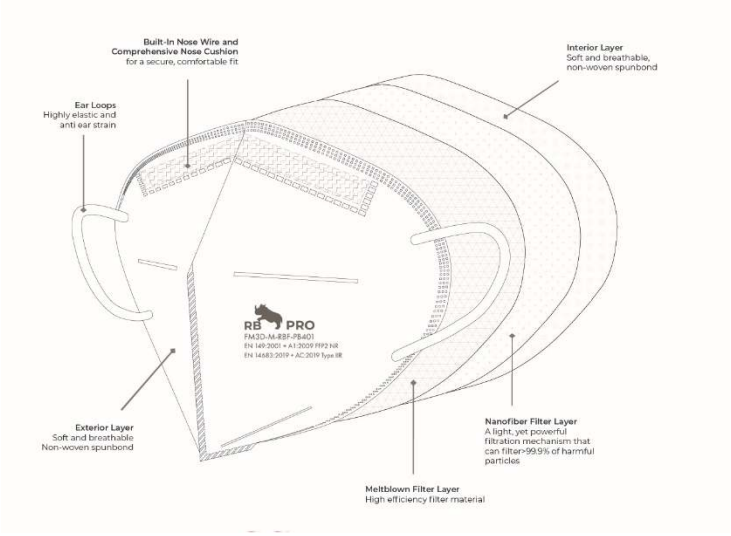
Component	***Material name***	***Composition***	***CAS No.***	***Manufacturer***
Outer layer	*PP Spun bond Nonwoven Fabrics*	*Polypropylene (99.999%)*	*9003-07-0*	*Shanghai Fengwei Nonwovens Co. Ltd.* *Address: No. 8255 Tingfeng Road, Fengjing Industry Part, Shanghai China* *Tel: +86-21-57353707* *Fax: +86-21-57351927* *mobile.: +86-15021627921* *E-mail: //www.fw-wf.com*

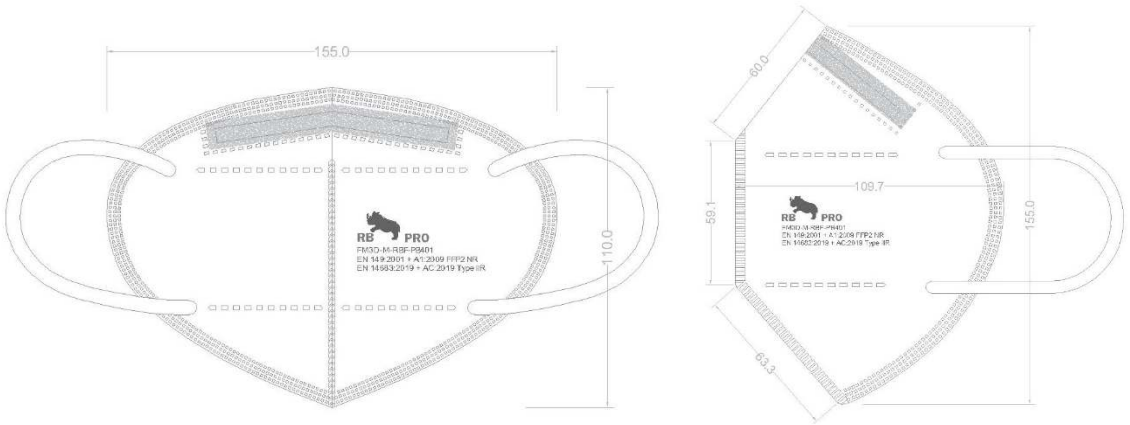
Middle layer	*Melt-Blown*	*Polypropylene (100%)*	*9003-07-0*	*Shanghai Kingfo Industrial Co.,Ltd.* *Address: No.28, Linsheng RD, Tinglin Industrial Area, Jinshan District, Shanghai, China* *Tel: +86-21-37910988-8019* *Fax: +86-21-37910922* *E-mail: dgz@clnonwoven.com*
Filter layer	*Pet Nanofiber Non-Woven Fabrics*	*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* *Fax: +86-021-57742235* *E-mail: Toby@newtech-textile.com*
Inner layer	*PP Spun bond Nonwoven Fabrics*	*Polypropylene (99.999%)*	*9003-07-0*	*Shanghai Fengwei Nonwovens Co. Ltd.* *Address: No. 8255 Tingfeng Road, Fengjing Industry Part, Shanghai China* *Tel: +86-21-57353707* *Fax: +86-21-57351927* *mobile.: +86-15021627921* *E-mail: //www.fw-wf.com*
Ear loop	*Nylon Spandex 4.8mm ear loop*	*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: hengsen9988@163.com*
Nose bar	*Slow Rebound High-Density 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, DongGuan City, Guangdong, China* *Tel: +86-15816835545* *E-mail: 402810814@qq.com*
Nose bridge	*Galvanized Iron Wire Nose Bridge Strip*	*Iron (75%)* *Polypropylene (25%)*	*7439-89-6* *9003-07-0*	*Haosen Hardware Plastic Products Co., Ltd.* *Address: 4th C -Building, Nanbangtong Industry Park, Songyuan Community, Guanlan Street, Longhua New District, Shenzhen Guandong, China* *Tel: +86-755-29012356* *E-mail: Shengyang0920@163.com*

Table 2. Product configuration

	Part description	Diameters (mm x mm)	Weight (g)
1	Outer layer	233 x 126	1.703
2	Middle layer	233 x 126	0.852
3	Filter layer	233 x 126	1.022
4	Inner layer	233 x 126	0.852
5	Ear loop	195 (left), 195 (right)	0.985
6	Nose bar	100 x 10	0.724
7	Nose bridge	90 x 5	0.717
		Total Weight (g)	6.855

Figure 1. Schematic diagram of face mask





Product photo of the face mask

Product photo of package

3. BIOLOGICAL ENDPOINTS NEEDED TO BE CONSIDERED

RB PRO SURGICAL RESPIRATOR is expected to be worn for less 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*
Ear loop	*Direct contact*	*Intact skin (area around ears)*	*< 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*	*Cyto toxicity*		*Irritation or intracutaneous reactivity*	*Material mediated pyrogenicity*	*Acute Systemic toxicity*	*Sub Acute toxicity*	*Sub Chronic 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*	*Outer layer* *Middle layer* *Inner layer* *Nose bridge*	*No* *No* *Yes* *No*	*Polypropylene 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 polypropylene is not classifiable as to its carcinogenicity to humans (Group 3) based on no adequate human data and inadequate animal data.*
Polyethylene Terephthalate	*25038-59-9*	*Filter 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*	*Ear loop*	*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*	*Ear loop*	*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.*

5. MANUFACTURING PROCESS AND STERILIZATION

5.1 Manufacturing of components

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

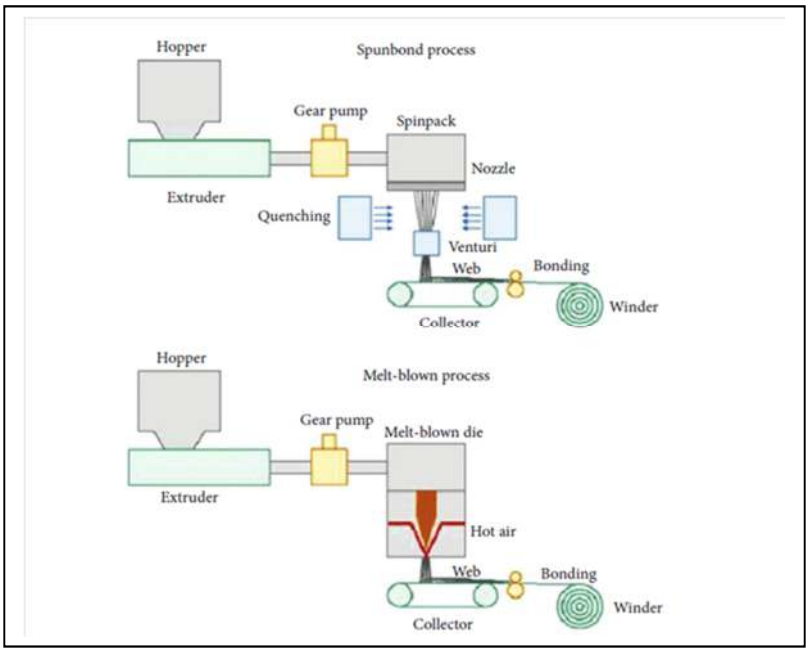


Table 5. Manufacturing process of components of RB PRO SURGICAL RESPIRATOR as provided by the manufacturer

No	*Component*		*Chemical Constituent*	*Production Process/Technology*
1	*Mask main body*	*Outer layer*	*Polypropylene*	*Spunbond-typed polymer extrusion technology to produce spunbond non-woven PP fabric (refer to Figure 2. Spunbond process).*
		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.*
		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.*

		Inner layer	*Polypropylene*	*Spunbond-typed polymer extrusion technology to produce spunbond non-woven PP fabric (refer to Figure 2. Spunbond process).*
2	*Ear loop*		*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*		*Iron, Polyethylene*	*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 RB PRO SURGICAL RESPIRATOR 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 ear loop) 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 ear loop 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 cleaning steps involved on the product while trial run was performed before each job order or machine runs for the first time to ensure normal operation of the machine.

It is indicated that no treatment and sterilisation measure has been employed during the production of the Mask. The finished product (RB PRO SURGICAL RESPIRATOR) is also indicated to be provided non-sterile and hence no sterilization residues, by-product and degradation product generated during sterilisation were expected to be present in the finished product.

The manufacturing setting, L&T International Group Philippines, Inc., was certified according to ISO 13485:2016 for the Manufacturing and Distribution of Medical Face Mask by third party certification organization (TÜV SÜD Certificate No. Q6 110165 001 Rev. 00 / Report No. MNL2021040001 with validity till 2024-12-06). 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, L&T International Group Philippines, Inc., in supporting to this biological evaluation of RB PRO SURGICAL RESPIRATOR 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*	*1. Outer Layer 50gsm PP Non Woven MSDS*
		ISO 10993-5 test report	*SDWH-M202000609-1-En (Report No.: SDWH-M202000609-1(E) Amd01)*
		ISO 10993-10 test report- skin irritation	*SDWH-M202000609-3-En (Report No.: SDWH-M202000609-3 (E) Amd01)*
		ISO 10993-10 test report- skin sensitization	*SDWH-M202000609-2-En(1) (Report No.: SDWH-M202000609-2(E) Amd01)*
	Middle layer	*Material MSDS*	*2. Filter -Meltblown MSDS*
		ISO 10993-5 test report	*2 . Filter Layer Meltblown 25gsm Nonwoven ISO10993 -5 (Report No.: SSMT-R-2021-00348-01B)*
	Filter layer	*Material MSDS*	*3 . PET Nano-fiber Non-woven (1) (3) (1)*
		ISO 10993-5 test report	*3. Nanofiber Pet 30gsm Non Woven ISO10993 -5 (Report No.: SSMT-R-2021-00351-01B)*
	Inner layer	*Material MSDS*	*4. Inner Layer 25gsm SDS*
		ISO 10993-5 test report	*SDWH-M202000609-1-En (Report No.: SDWH-M202000609-1(E) Amd01)*
		ISO 10993-10 test report- skin irritation	*SDWH-M202000609-3-En (Report No.: SDWH-M202000609-3 (E) Amd01)*
		ISO 10993-10 test report- skin sensitization	*SDWH-M202000609-2-En(1) (Report No.: SDWH-M202000609-2(E) Amd01)*
	Ear loop	*Material MSDS*	*7. Earloop EL-MSDS-3-7mm-20210409 Earloop (1) (2)*
		ISO 10993-10 test report- skin irritation	*2-Ear Loop-SSMT-R-2021-01981-02A-ISO 10993-10 Skin Irritation Test-ear loop-210709 (1) (1) (Report No.: SSMT-R-2021-01981-02A)*
		ISO 10993-10 test report- skin sensitization	*2. Ear Loop SSMT-R-2021-01981-03A-ISO 10993-10 Skin Sensitization Test-ear loop-210719 (1) (Report No.: SSMT-R-2021-01981-03A)*
	Nose bar	*Material MSDS*	*5. Nose Bar -MSDS-EN-20210618 (1) (1)*
		ISO 10993-5 test report	*5. Nose Sponge White - In Vitro Cytotoxicity ISO 10993 5 SSMT-R-2022-02259-01B (Report No.: SSMT-R-2022-02259-01B)*

		ISO 10993-10 test report- skin irritation	*3.Nose Sponge White - Skin Irritation Test ISO 10993-10 SSMT-R-2022-02259-02B (Report No.: SSMT-R-2022-02259-02B)*
		ISO 10993-10 test report- skin sensitization	*3. Nose Sponge -Skin Sensitization test 1SO10993-10 SSMT-R-2022-02259-03B (Report No.: SSMT-R-2022-02259-03B)*
	Nose bridge	*Material MSDS*	*6. Nose Bridges MSDS-EN0001 昊森五金 147181 NOSE WIRE (3)*
		ISO 10993-5 test report	*6. Nose Wire ISO10993-5 Haosen (Report No.: SSMT-R-2021-04257-01B)*
	Whole mask	*ISO 10993-5 test report*	*7. Whole Mask SSMT-R-2021-01994-01A-ISO 10993-5 In Vitro Cytotoxicity Test-mask-210701 (1).pdf (Report No.: SSMT-R-2021-01994-01A)*
			7. WHOLE MASK SSMT-R-2021-04736-01A Vitro Cytotoxicity ISO 10993-5 (1).pdf (Report No.: SSMT-R-2021-04736-01A)
Production	*Nonwoven*	*Production workflow*	*Brief Description of Production Process of Materials_MB_SP*
	Filter layer	*Production workflow*	*Brief Introduction of spunbond-electrospinning PET Nano*
	Nose bar	*Production workflow*	*Brief Description of Production Process of Materials_MB_SP*
	Nose bridge	*Production workflow*	*Brief Description of Production Process of Materials_MB_SP*
	Finished product	*Assembly / production of finished product*	*Brief Description of Production Process of Materials_MB_SP*
Product	*N/A*	*Dimension and weight of components*	*Info sheet-biocompatibility RB PRO 061622*
		Product photo.	*rb pro 1.png, rb pro 2.png, rb pro 3.png, rb pro 4.png*
Test Reports	*N/A*	*Microbial cleanliness / Bioburden test report*	*[RBProPH]T32120310647SN (Report No.: T32120310647SN)*
		Bacterial filtration efficiency (BFE) test report	*[RBProPH]T32120310647SN (Report No.: T32120310647SN)*
		Particulate filtration efficiency (PFE) test report	*[PB401) SL52125322323401TX EN149 (Report No.: SL52125322323401TX)*
		Differential pressure/ Breathability test report	*[RBProPH]T32120310647SN (Report No.: T32120310647SN) / [PB401) SL52125322323401TX EN149 (Report No.: SL52125322323401TX)*
		Resistance to penetration by synthetic blood/ Splash resistance test report	*[RBProPH]T32120310647SN (Report No.: T32120310647SN)*
		Flammability test report	*[PB401) SL52125322323401TX EN149 (Report No.: SL52125322323401TX)*
Miscellaneous	*Certification*	*ISO 13485 Certificate*	*LT International Group Phils. Inc. _RELEASED Certificate (Certificate No. Q6 110165 0001 Rev. 00)*

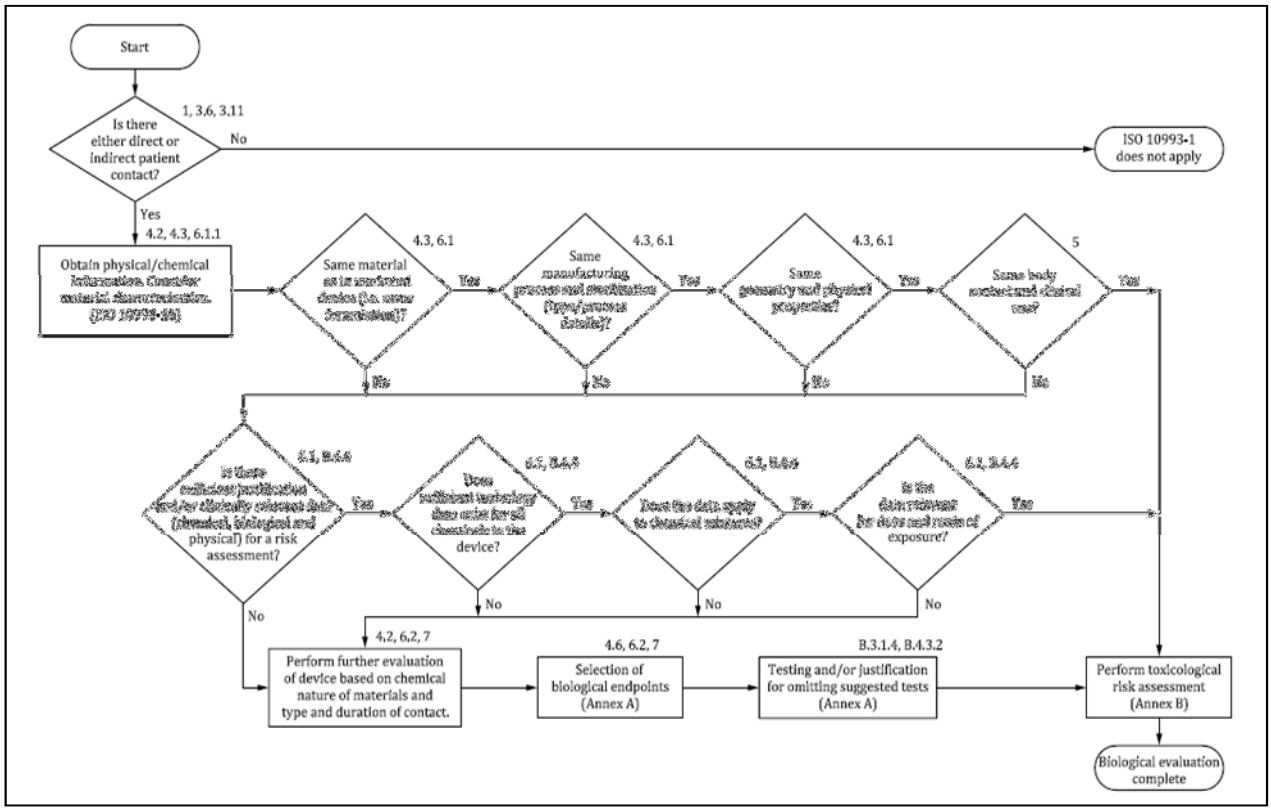
7. AVAILABILITY AND GAP ANALYSIS FOR BIOLOGICAL ENDPOINTS

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, ear loop, nose bar and nose bridge*	• *Only the inner layer, ear loop and nose bar directly contact with the intact skin.* • *The inner layer is composed of 100% of polypropylene.* • *The nose bar is indicated to be consisted of 100% of polyurethane.* • *The ear loop is consisted of nylon and 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 & inner layer (the same set of test report), middle layer, filter layer, nose bar, nose bridge and whole mask*	• *All the tested samples indicated a negative cytotoxicity result.* • *Only the inner layer, ear loop and nose bar directly contact with the intact skin.* • *No cytotoxicity test has been performed on ear loop.* • *The ear loop 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 & inner layer (the same set of test report), ear loop and nose bar*	• *Only the inner layer, ear loop 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 & inner layer (the same set of test report), ear loop and nose bar*	• *Only the inner layer, ear loop 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, ear loop, 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 ********