10A LIMITED
ROOM 1001-1005, 10/F NANYANG PLAZA, 57 HUNG TO ROAD, KWAN TONG, HK

The following sample was submitted and identified by the client as 10A NanoGO Face Mask Lotus Plus P401.

| | | |
|---|---|---|
| SGS Report No. | : | HKHC2109007389HC (T32120290619SN) |
| SGS Case No. | : | HKHC210800002665-102 (CA321202939489) |
| Style/Item No. | : | FM3D-M-LOT-P401 |
| Country of Origin | : | Hong Kong |
| Country of Destination | : | Hong Kong |
| Manufacturer | : | 10A Limited |
| Labeled Age Grading | : | Adult |
| Sample Receiving Date | : | Aug 30, 2021 – Sep 20, 2021 |
| Test Period | : | Aug 30, 2021 – Sep 30, 2021 |

**Test 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.

**Test 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, CBiol
European Registered Toxicologist (ERT)
Diplomate American Board of Toxicology (DABT)

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## 1. INTRODUCTION

The product 10A NanoGO Face Mask Lotus Plus P401 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 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 P401 is a medical face mask with ear loop for wearing and a nose piece/ nose bar design for fitting the face mask around the nose. The mask is consisted of 7 components: white spunbond non-woven hydrophobic fabric outer layer, white melt-blown non-woven fabric middle layer, white filter layer, white spunbond non-woven hydrophilic inner layer, elastic ear loops, nose bridge and nose bridge. 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.*<br><br>*Address: No. 332, Ouhai Avenue, Wenzhou, Zhejiang, 325014 P. R. China*<br>*Tel: +86-577-86763780-8028*<br>*E-mail: lww1638@163.com*<br>*Emergency no.: +86-577-86763780-8028* |

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| | | | | |
|---|---|---|---|---|
| ***Middle layer*** | *Melt-Blown* | *Polypropylene (100%)* | *9003-07-0* | *Shanghai Kingfo Industrial Co.,Ltd.*<br>*Address: No.28, Linsheng RD, Tinglin Industrial Area, Jinshan District, Shanghai, China*<br>*Tel: +86-21-37910988-8019*<br>*E-mail: 30472943l@qq.com*<br>*Emergency no.:+86-13816811941* |
| ***Filter layer*** | *NanoGO™ Nanofiber Non-Woven Fabrics (NanoGO™ PET) / PET Nanofiber Non-Woven Fabrics 3Y0209340010003/04/06* | *Polyethylene Terephthalate (99.4%)*<br>*Polyvinyl Alcohol (0.6%)* | *25038-59-9*<br>*9002-89-5* | *Newtech Textile Technology Development (Shanghai) Co., Ltd.*<br>*Address: 318B, Lianyang Road Songjiang District, Shanghai, China*<br>*Tel: +86-021-57742231*<br>*Fax: +86-021-57742235*<br>*Emergency no.: +86-021-57742231* |
| ***Inner layer*** | *PE+PP Bicomponent Nonwovens* | *Polypropylene (50%)*<br>*Polyethylene (50%)* | *9003-07-0*<br>*9002-88-4* | *Shanghai Kingfo Industrial Co.,Ltd.*<br>*Address: No.28, Linsheng RD, Tinglin Industrial Area, Jinshan District, Shanghai, China*<br>*Tel: +86-021-37910988-8019*<br>*E-mail: 30472943l@qq.com*<br>*Emergency no.:+86-13816811941* |
| ***Ear loop*** | *Earloop for masks (3MM-7MM)* | *Nylon (70%)*<br>*Spandex (30%)* | *32131-17-2*<br>*9009-54-5* | *Dongguan Yusen Industrial Co., Ltd.*<br>*Address: No. 48 BingFu road, ShuiBian village, Hengli town, DongGuan City, Guangdong, China*<br>*Tel: +8613712904008*<br>*E-mail: hengsen9988@163.com*<br>*Emergency no.: +86-769-83937783* |
| ***Nose bar*** | *Slow Rebound High Density Grey Sponge* | *Polyurethane (100%)* | *9009-54-5* | *Dongguan Runfu Polymer Material Co., Ltd.*<br>*Address: No. 3 Office Building, Jujia Science & Technology Park, Runzi Garden Village, Xiegang Town, DongGuan City, Guangdong, China.*<br>*Tel: +86-15816835545*<br>*E-mail: 402810814@qq.com*<br>*Emergency no.: +86-769-83065415* |
| ***Nose bridge*** | *Galvanized Iron Wire Nose Bridge Strip* | *Iron (50%)*<br>*Polyethylene (45%)*<br>*Polypropylene (5%)* | *7439-89-6*<br>*9002-88-4*<br>*9003-07-0* | *Danyang Winpowder Wire & Cable Mfg. Co., Ltd.*<br>*Address: Lingkou Industrial Park, Danyang City, Jiangsu, China*<br>*Tel: +86-511-86769009*<br>*E-mail: zhuangsheng@green-cable.com*<br>*Emergency no.: N/A* |

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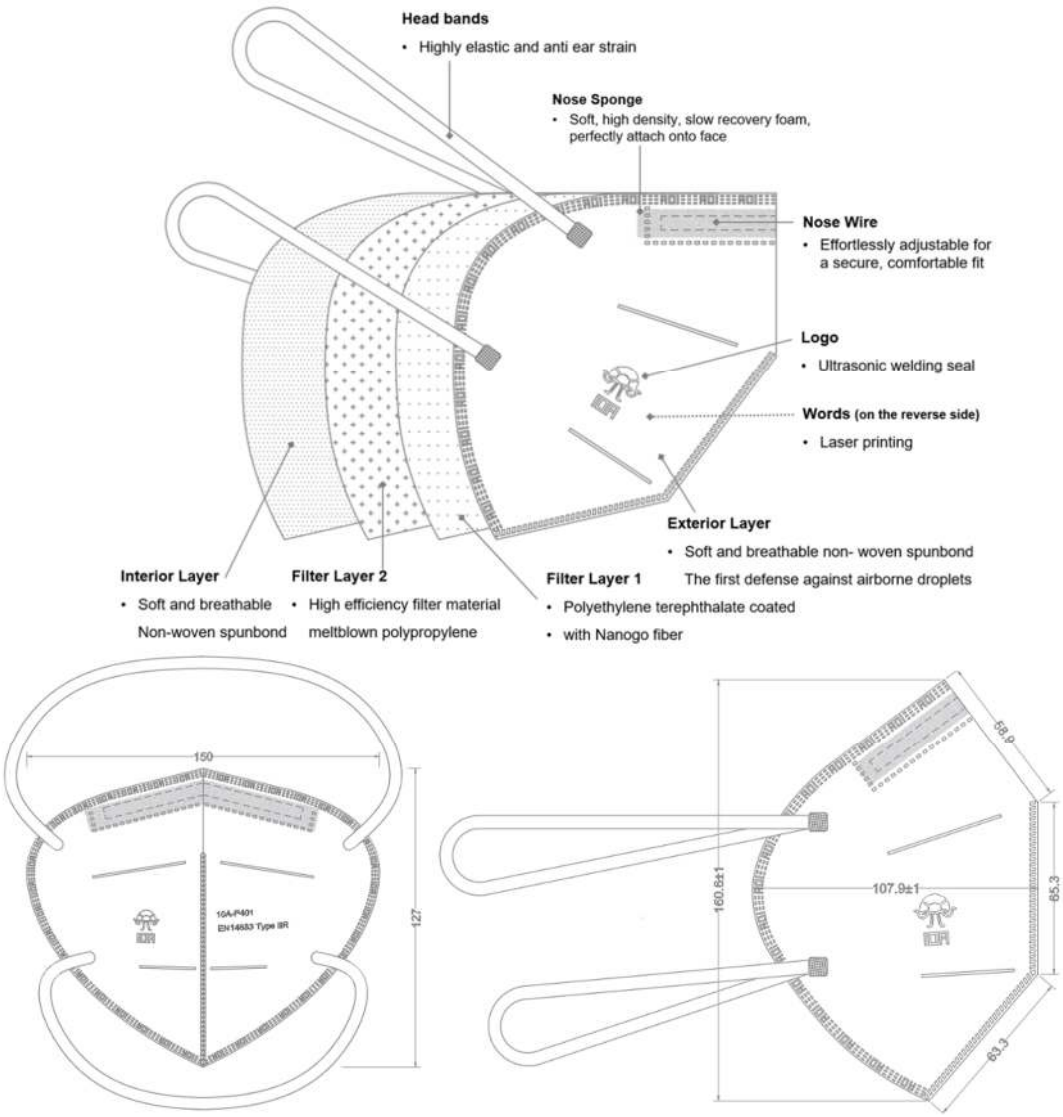
*Table 2. Product configuration*

| | Part description | Diameters (mm x mm) | Weight (g) |
|---|---|---|---|
| 1 | *Outer layer* | *233 x 126* | *1.671* |
| 2 | *Middle layer* | *233 x 126* | *0.84* |
| 3 | *Filter layer* | *233 x 126* | *1.137* |
| 4 | *Inner layer* | *233 x 126* | *0.981* |
| 5 | *Ear loop* | *280 (upper), 250 (lower)* | *1.64* |
| 6 | *Nose bar* | *100 x 10* | *0.66* |
| 7 | *Nose bridge* | *83 x 5* | *0.494* |
| | | **Total Weight (g)** | *7.423* |

*Figure 1. Schematic diagram of face mask*

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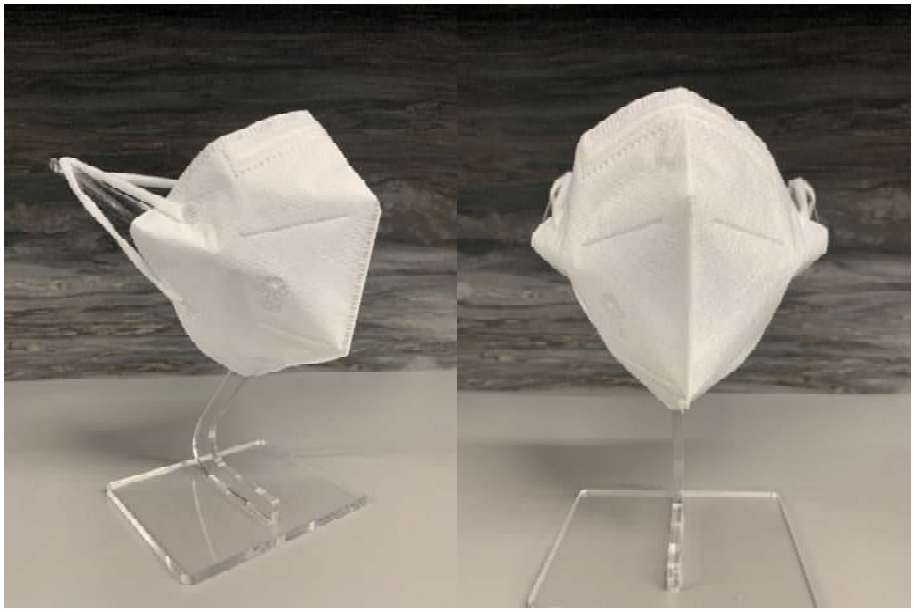
*Product photo of the face mask*



*Product photo of package (25 pieces per pack)*

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## 3. BIOLOGICAL ENDPOINTS NEEDED TO BE CONSIDERED

10A NanoGO Face Mask Lotus Plus P401 packaging indicates the recommended wearing time is < 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* | *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 5.

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*Table 4. Toxicological/ Chemical profile of constituents*

| ***Chemical Name*** | ***CAS No.*** | ***Materials*** | ***Direct contact with skin*** | ***Toxicological profile*** |
|---|---|---|---|---|
| *Polyethylene Terephthalate* | *25038-59-9* | *Outer layer*<br>*Filter layer* | *No*<br>*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.* |
| *Polypropylene* | *9003-07-0* | *Middle layer*<br>*Inner layer*<br>*Nose bridge* | *No*<br>*Yes*<br>*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.* |
| *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* |

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| | | | | *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.* |
| *Polyethylene* | *9002-88-4* | *Inner layer*<br>*Nose bridge* | *Yes*<br>*No* | *A vinyl polymer made from ethylene. 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. Polyethylene is used in a variety of medical devices including implants and prostheses.* |
| *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.*<br>*The nose bar is in grey color but the supplier of the nose bar indicated the nose bar is consisted of 100% of polyurethane and supported with submitted SDS. It is the responsibility of the* |

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|---|---|---|---|---|
| | | | | *supplier/ manufacturer to provide truthful and valid document that this evaluation based upon. If it is not the case, it will void this assessment.* |
| *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

The outer layer and inner layer are formed by spunbond. The middle layer is produced by melt-blowing. Filter layer is indicated to be produced by modified spunbond machine that nanofibers are generated in a high-voltage electrostatic field from the polymer solution in the generator and collected into a nanofiber layer on the PET nonwoven on the rotated collector. Ear loop is fabricated from an elongated layer of malleable material. Nose bridge is made with iron wire embedded in plastic. Nose bar is indicated to be consisted of polyurethane foam.
Table 1 show the chemical constituents of the components and it is indicated that no additives (antioxidants, UV stabilizers, dyes etc.) and processing aids (solvents, lubricants, antifoaming agents, etc.) have been added during the manufacturing process.
No certificate and audit report on the manufacturing setting, 10A Limited, has been provided for this evaluation. The product has to be manufactured under setting with QMS for quality. It is indicated that there was no cleaning step during the assembly / packaging process and hence introduction of contaminants was not expected. The finished product is also indicated to be provided non-sterile and hence no sterilization residuals, by-product and degradation were expected.

## 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 P401 is summarized in Table 5. 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 5. Submitted dataset and document by the manufacturer*

| ***Category*** | ***Subcategory*** | ***Document description*** | ***File name (Report No.)*** |
|---|---|---|---|
| *Materials* | *Outer layer* | *Material MSDS* | *PET 英文版本; PET 中文版本* |
| | | *ISO 10993-5 test report* | *1-Outer Layer PET 50gsm Nonwoven 10993-5 ENG (Report No.: SSMT-R-2021-01802-01B)* |
| | | *ISO 10993-10 test report- skin irritation* | *5-Outer Layer PET 50gsm Nonwoven 10993-10 SI ENG (Report No.: SSMT-R-2021-01974-01B)* |

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| | | | |
|---|---|---|---|
| | | *ISO 10993-10 test report- skin sensitization* | *5-Outer Layer PET 50gsm Nonwoven 10993-10 SS ENG (Report No.: SSMT-R-2021-01974-02B)* |
| | *Middle layer* | *Material MSDS* | *4-Middle Layer-MB SDS* |
| | | *ISO 10993-5 test report* | *2-Filter Layer MB 25gsm Nonwoven ENG (Report No.: SSMT-R-2021-00348-01B)* |
| | *Filter layer* | *Material MSDS* | *5-Filter Layer NanoGO SDS For PET Nano-fiber Non-woven* |
| | | *ISO 10993-5 test report* | *3-Nanofiber PET 30gsm with GO 30ppm Nonwoven ENG (Report No.: SSMT-R-2021-00349-01B)* |
| | *Inner layer* | *Material MSDS* | *3-Inner Layer-EP SDS* |
| | | *ISO 10993-5 test report* | *4-Inner Layer EP 25gsm Nonwoven 10993-5 ENG (Report No.: SSMT-R-2021-00350-0lB)* |
| | | *ISO 10993-10 test report- skin irritation* | *1-Inner Layer EP 25gsm Nonwoven 10993-10 SI ENG (Report No.:SSMT-R-2021-01973-01B)* |
| | | *ISO 10993-10 test report- skin sensitization* | *1-Inner Layer EP 25gsm Nonwoven 10993-10 SS ENG (Report No.:SSMT-R-2021-01973-02B)* |
| | *Ear loop* | *Material MSDS* | *2-Earloop-EL-MSDS-3-7mm-20210409* |
| | | *ISO 10993-10 test report- skin irritation* | *4-Ear Loop-SSMT-R-2021-01981-02A-ISO 10993-10 Skin Irritation Test-ear loop-210709 (Report No.:SSMT-R-2021-01981-02A)* |
| | | *ISO 10993-10 test report-skin sensitization* | *4-Ear Loop-SSMT-R-2021-01981-02A-ISO 10993-10 Skin Irritation Test-ear loop-210709 (Report No.:SSMT-R-2021-01981-03A)* |
| | *Nose bar* | *Material MSDS* | *1-Nose Bar-MSDS-grey nose sponge-Runfu-210918* |
| | | *ISO 10993-5 test report* | *2-Nose Bar-GZF21-005461-01 SZ RSTS ISO 10993-10 english (Report No.: GZF21-005461-01)* |
| | | *ISO 10993-10 test report- skin irritation* | *2-Nose Bar-GZF21-005461-01 SZ RSTS ISO 10993-10 english (Report No.: GZF21-005461-01), 2-Nose Bar-GZF21-005461-02 SZ RSTS ISO 10993-10 english (Report No.: GZF21-005461-02)* |
| | | *ISO 10993-10 test report- skin sensitization* | *3-Nose Bar-GZF21-005464-01 SZ RSTS ISO 10993-10 english (Report No.: GZF21-005464-01), 3-Nose Bar-GZF21-005464-03 SZ RSTS ISO 10993-10 english (Report No.: GZF21-005464-03)* |
| | *Nose bridge* | *Material MSDS* | *6-Nose Bridge-MSDS* |
| | *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 (Report No.: SSMT-R-2021-01994-01A Amd01)* |
| *Production* | *Nonwoven* | *Production workflow* | *Info sheet-biocompatibility P401-v0920* |
| | *Filter layer* | *Production workflow* | *brief introduction of spunbond-electrospinning, NanoGO 普通纳米纤维介绍* |
| | *Nose bar* | *Production workflow* | *Info sheet-biocompatibility P401-v0920* |
| | *Nose bridge* | *Production workflow* | *Email correspondence* |
| | *Finished product* | *Assembly / production of finished product* | *Email correspondence* |

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| | | | |
|---|---|---|---|
| *Product* | *N/A* | *Dimension and weight of components* | *Info sheet-biocompatibility P401-v0920, Medical Device File - 10A Lotus Plus P401, Email correspondence* |
| | | *Product and packing photo.* | *P401, P401-2, P401-3, P401 Package Draft, Medical Device File - 10A Lotus Plus P401* |
| *Test Reports* | *N/A* | *Microbial cleanliness / Bioburden test report* | *T32120260434SN* |
| | | *Bacterial filtration efficiency (BFE) test report* | *T32120260434SN* |
| | | *Particulate filtration efficiency (PFE) test report* | *SL52105268360501TX* |
| | | *Differential pressure/ Breathability test report* | *T32120260434SN / SL52105268360501TX* |
| | | *Resistance to penetration by synthetic blood/ Splash resistance test report* | *T32120260434SN* |
| | | *Flammability test report* | *SL52105268360501TX* |
| *Miscellaneous* | *Certification* | *Certificate of compliance* | *N/A* |

## 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 6. 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 polypropylene and polyethylene.*<br>• *The nose bar is indicated to be consisted of 100% of polyurethane.*<br>• *The ear loop is consisted of nylon and spandex.*<br>• *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.*<br>• *There is no additive added and sterilization during the manufacturing process and hence issue of residual solvent, degradation and by-product is not expected.*<br>• *The manufacturing setting should be controlled under QMS to ensure quality while airborne contamination is controlled.* |
| *Cytotoxicity* | *ISO 10993-5 test report on outer layer, middle layer, filter layer, inner layer, nose bar and whole mask* | • *All the tested samples indicated a negative cytotoxicity result.*<br>• *No cytotoxicity test has been performed on ear loop and nose bridge.* |

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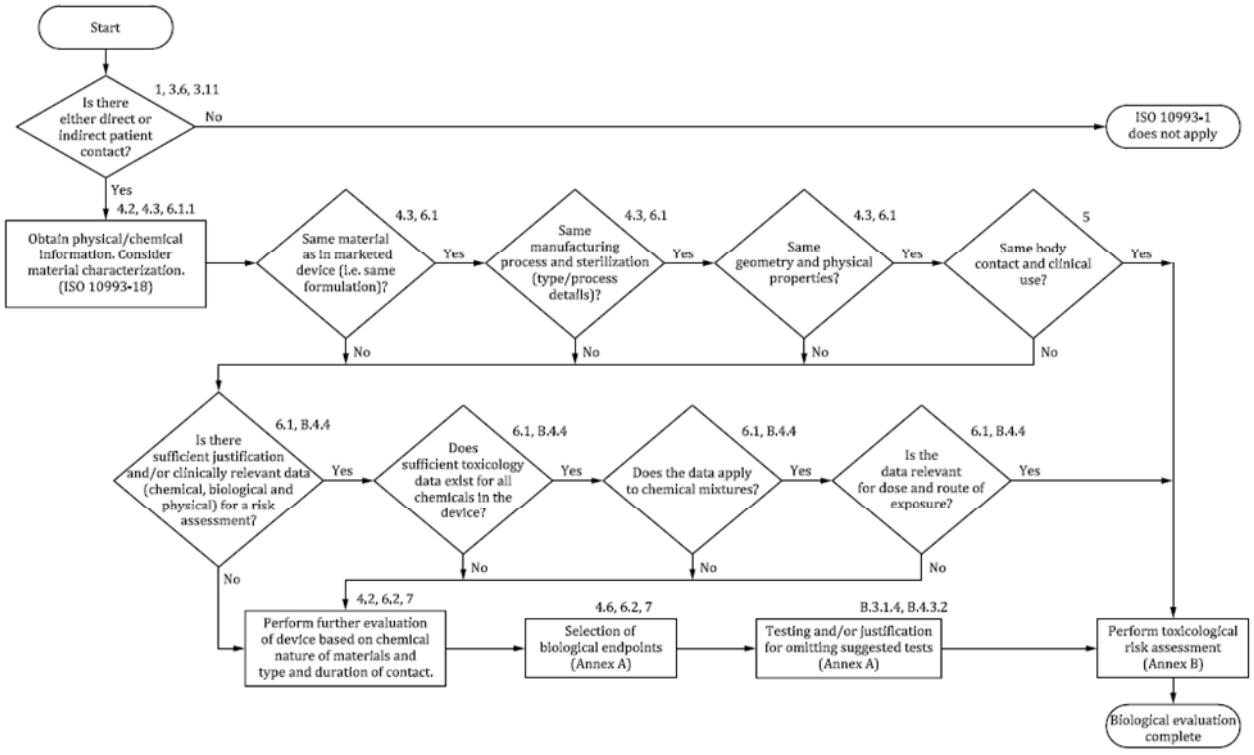
| | | |
|---|---|---|
| | | • *Nose bridge did not directly contact with the intact skin.*<br>• *The ear loop is consisted of nylon and spandex and has been well-received in the market.* |
| *Irritation or intracutaneous reactivity* | *ISO 10993-10 Skin irritation test report on outer layer, inner layer, ear loop and nose bar* | • *All the tested samples indicate a negative skin irritation result.*<br>• *The tested samples are not expected to raise a concern of skin irritation when used as intended.*<br>• *No skin irritation has been conducted on middle layer, filter layer and nose bridge but they did not directly contact with the intact skin.* |
| *Sensitization* | *ISO 10993-10 Skin sensitization test report on outer layer, inner layer, ear loop and nose bar* | • *All the tested samples indicate a negative skin sensitization result.*<br>• *The samples are not expected to raise a concern of skin sensitization when used as intended.*<br>• *No skin sensitization has been conducted on middle layer, filter layer and nose bridge but they did not directly contact with the intact skin.* |

*Figure 2. Summary of the Systematic Approach to this Biological Evaluation According to ISO 10993-1: 2018*

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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 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).

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

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