Prüfbericht-Nr.: *Test Report No.*:	**60376376 001**	**Auftrags-Nr.** *Order No.*:	**168264325**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.*:	N/A	**Auftragsdatum:** *Order date*:	May 11, 2020	

Auftraggeber: *Client*:	**K.Y. Health Medical Equipment Co., Ltd** 777 Wangcongdong Rd, Pidu, Chengdu, Sichuan, 610000, P.R. China
Prüfgegenstand: *Test item*:	DISPOSABLE FACE MASK
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	Y6002
Auftrags-Inhalt: *Order content*:	Type test
Prüfgrundlage: *Test specification*:	EN 14683:2019+AC:2019 except for clause 5.2.6

Wareneingangsdatum: *Date of receipt*:	May 11, 2020
Prüfmuster-Nr.: *Test sample No.*:	20206118
Prüfzeitraum: *Testing period*:	May 11, 2020 to May 22, 2020
Ort der Prüfung: *Place of testing*:	See page 3
Prüflaboratorium: *Testing laboratory*:	TÜV Rheinland (Shenzhen) Co., Ltd.
Prüfergebnis*: *Test result**:	Pass

See Attachment: Photo documentation for details.

geprüft von / *tested by*:

Javen Ke

May 22, 2020 Javen Ke/Assistant Project Engineer

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*:

Angela Ch

May 22, 2020 Angela Chen / Department Manager

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (6 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*N/T = not tested*

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**60376376 001**
Date of issue ..... :	**See cover page**
Total number of pages ..... :	**See cover page**
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address ..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name ..... :	**K.Y. Health Medical Equipment Co., Ltd**
Address ..... :	777 Wangcongdong Rd, Pidu, Chengdu, Sichuan, 610000, P.R. China
Test specification:	
Standard ..... :	EN 14683:2019+AC:2019
Test procedure ..... :	Type test
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_A
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description ..... :	DISPOSABLE FACE MASK
Trade Mark ..... :	K.Y.Health
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	Y6002
Classification ..... :	Type I

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (6 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden)	**Sichuan Testing Center of Medical Devices** No. 4-28, Xinye Road, High tech west Area, Chengdu, Sichuan, 611731, P.R.China

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

See attachment.

Testing

Date of receipt of test item(s)……: See cover page

Dates of tests performed……: See cover page

Possible test case verdicts:

- test case does not apply to the test object …… : N/A
- test object does meet the requirement…… : P (Pass)
- test object was not evaluated for the requirement … : N/E (collateral standards only)
- test object does not meet the requirement…… : F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies) ……: Same as the applicant

General product information:

1, The tested medical mask classified as type I.
2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report.
3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.
4**, Evaluation of splash resistance (Clause 5.2.4) was added per requirement of manufacturer.**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		**P**
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type I	**P**
5	**Requirements**		**P**
5.1	**General**		**P**
5.1.1	**Materials and construction**		**P**
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	3 ply designed with two layers of non-woven and one layer of meltblown.	**P**
	The medical face mask shall not disintegrate, split or tear during intended use.		**P**
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		**P**
5.1.2	**Design**		**P**
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		**P**
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	**P**
5.2	**Performance requirements**		**P**
5.2.1	**General**		**P**
	All tests shall be carried out on finished products or samples cut from finished products.		**P**
5.2.2	**Bacterial filtration efficiency (BFE)**		**P**
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	See appended table 5.2.2	**P**
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not such mask.	**N/A**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.	Same characteristics and same layer-composition declared by manufacturer.	**N/A**
	The lowest performing panel or area shall determine the BFE value of the complete mask	See above	**N/A**
5.2.3	**Breathability**		**P**
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	See appended table 5.2.3	**P**
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		**N/A**
5.2.4	**Splash resistance**		**P**
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	Type I mask. Evaluation was added per requirement of manufacturer. See appended table 5.2.4	**P**
5.2.5	**Microbial cleanliness (Bioburden)**		**P**
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	**P**
5.2.6	**Biocompatibility**		**N/E**
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.	The biocompatibility is not evaluated in this test report.	**N/E**
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.		**N/E**
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		**N/E**
	The test results shall be available upon request.		**N/E**
6	**Marking, labelling and packaging**		**P**
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See attachment.	**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The following information shall be supplied:		**P**
	a) number of this European Standard;		**P**
	b) type of mask (as indicated in Table 1).		**P**
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	**Test Specimen no.:**	**Dimension of the test specimen L x W (mm x mm)**	**test area (cm²)**	**Flow rate (l/min)**	**Mean of the total plate counts of the two positive controls**	**Mean plate count of the negative controls**	**BFE for each test specimen (%)**	**Remarks**
20206118	1	160×154	63.6	28.3	1760	0	99.43	--
	2	159×153	63.6	28.3			99.30	--
	3	159×153	63.6	28.3			99.13	--
	4	160×155	63.6	28.3			99.36	--
	5	160×154	63.6	28.3			99.43	--

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 16 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: inside of mask.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.3	TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	**Test Specimen number-Test area number**	**Differential pressure for each test area (Pa/cm²)**	**The averaged differential pressure for each test specimen (Pa/cm²)**	**Flow rate (l/min)**	**Remarks**
20206118	1-1	25.0	27.5	8.0	--
	1-2	27.5		8.0	--
	1-3	26.8		8.0	--
	1-4	30.8		8.0	--
	1-5	27.6		8.0	--
	2-1	24.6	23.5	8.0	--
	2-2	24.7		8.0	--
	2-3	21.0		8.0	--
	2-4	24.0		8.0	--
	2-5	23.3		8.0	--
	3-1	25.0	25.3	8.0	--
	3-2	20.7		8.0	--
	3-3	27.1		8.0	--
	3-4	27.6		8.0	--
	3-5	26.0		8.0	--
	4-1	27.1	27.7	8.0	--
	4-2	26.7		8.0	--
	4-3	25.6		8.0	--
	4-4	28.6		8.0	--
	4-5	30.6		8.0	--
	5-1	29.7	26.4	8.0	--
	5-2	25.4		8.0	--
	5-3	24.2		8.0	--
	5-4	26.5		8.0	--
	5-5	26.1		8.0	--

Supplementary information:
Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

atmosphere prior to testing.

5.2.4	TABLE: Splash resistance			P
Batch/ lot no.:	**Test mask no.:**	**The material of tested mask**	**Test result (Pass/fail)**	**Remarks**
20206118	**1**	**See clause 5.1.1 for detail**	**Pass**	--
	2		**Pass**	--
	3		**Pass**	--
	4		**Pass**	--
	5		**Pass**	--
	6		**Pass**	--
	7		**Pass**	--
	8		**Pass**	--
	9		**Pass**	--
	10		**Pass**	--
	11		**Pass**	--
	12		**Pass**	--
	13		**Pass**	--
	14		**Pass**	--
	15		**Pass**	--
	16		**Pass**	--
	17		**Pass**	--
	18		**Pass**	--
	19		**Pass**	--
	20		**Pass**	--
	21		**Pass**	--
	22		**Pass**	--
	23		**Pass**	--
	24		**Pass**	--
	25		**Pass**	--
	26		**Pass**	--
	27		**Pass**	--
	28		**Pass**	--

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

	29		**Pass**	**--**
	30		**Pass**	**--**
	31		**Pass**	**--**
	32		**Pass**	**--**

Supplementary information:

1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

2, The description of target area tested: the centre of the specimen.

3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab .

4, The temperature and relative humidity for testing: 21 °C and 80 %.

5, Description of any pre-treatment techniques used: N/A.

5.2.5	**TABLE: Microbial cleanliness (Bioburden)**			**P**
Batch/ lot no.:	**Mask(under test) no.:**	**Weight of each mask (g)**	**Total bioburden per individual mask (CFU/g)**	**Remarks**
20206118	**1**	**3.1**	**16**	**--**
	2	**3.0**	**6**	**--**
	3	**2.9**	**6**	**--**
	4	**2.9**	**10**	**--**
	5	**3.0**	**7**	**--**

Supplementary information:

End of EN 14683 test report

Product: DISPOSABLE FACE MASK

Type Designation: Y6002

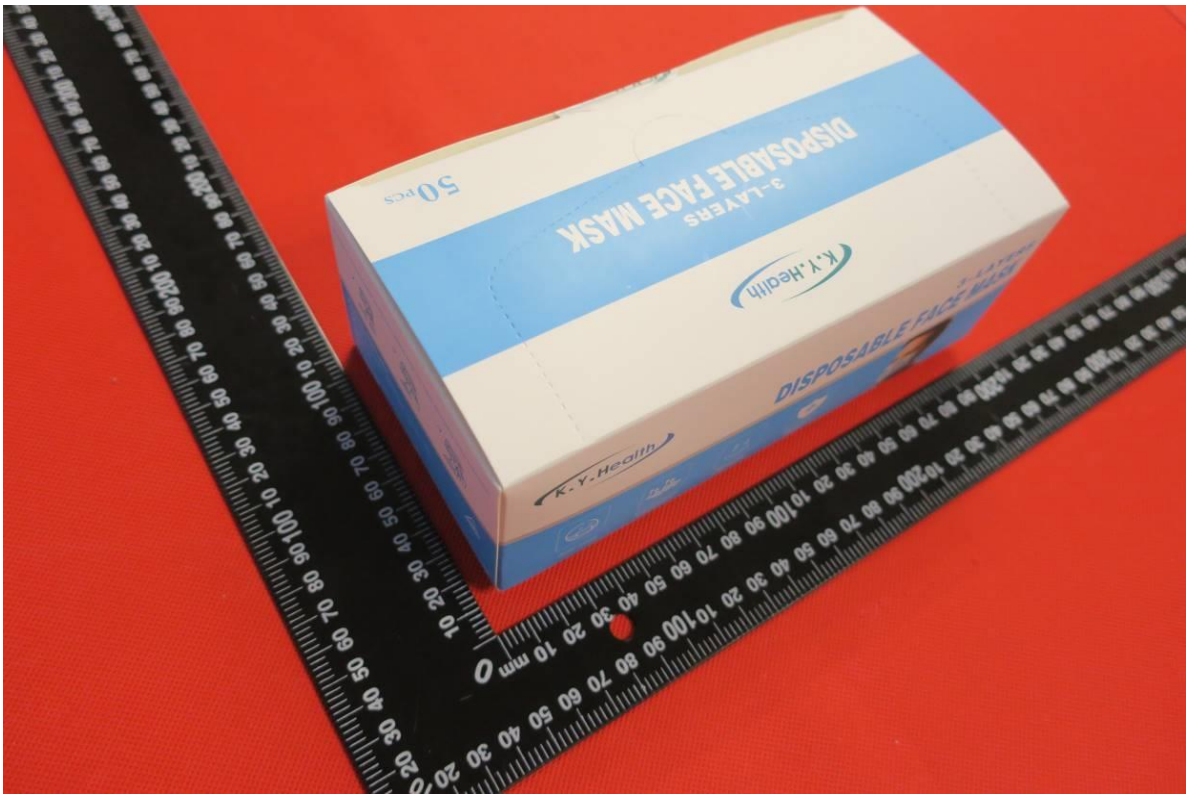

Figure 1 View of packaging box for mask
(Final marking of package box refer to Figure 7 to Figure 10 below)

Figure 2 View of packaging for mask in box

Product: DISPOSABLE FACE MASK

Type Designation: Y6002

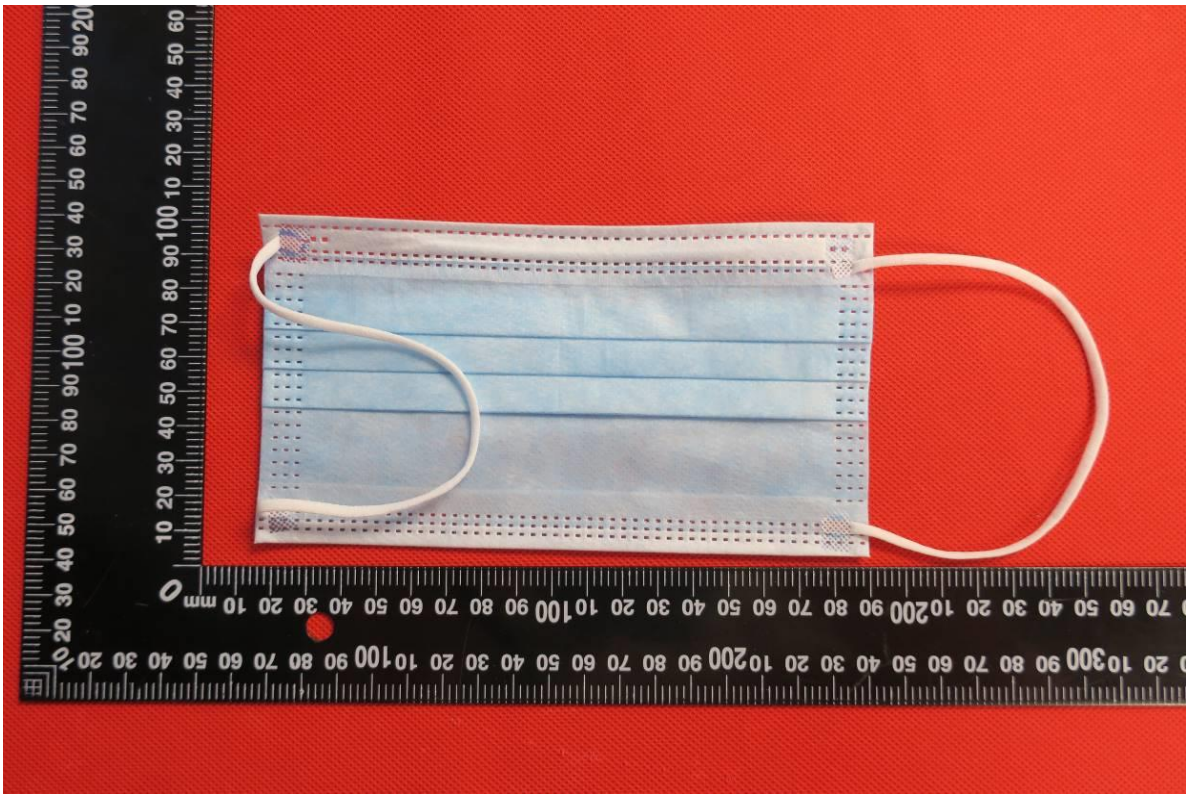

Figure 3 View of mask

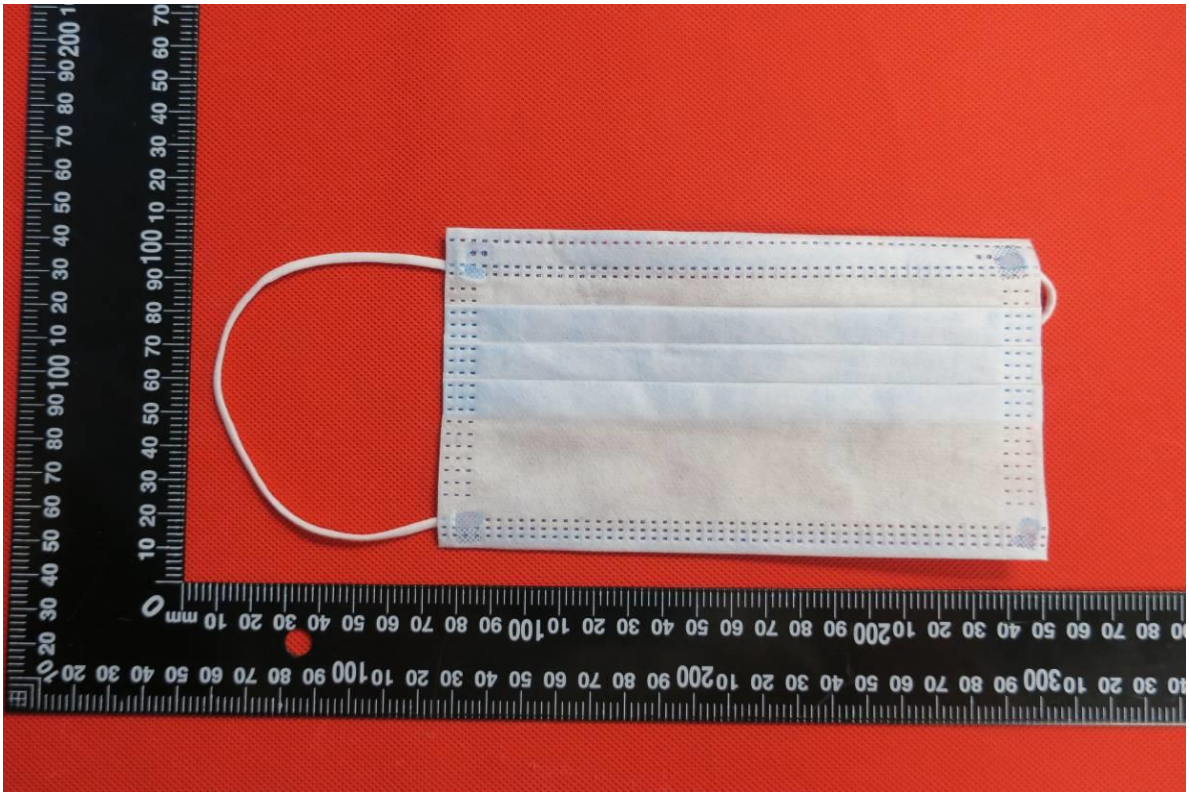

Figure 4 View of mask

Product: DISPOSABLE FACE MASK

Type Designation: Y6002

Figure 5 Inner view of mask - layers

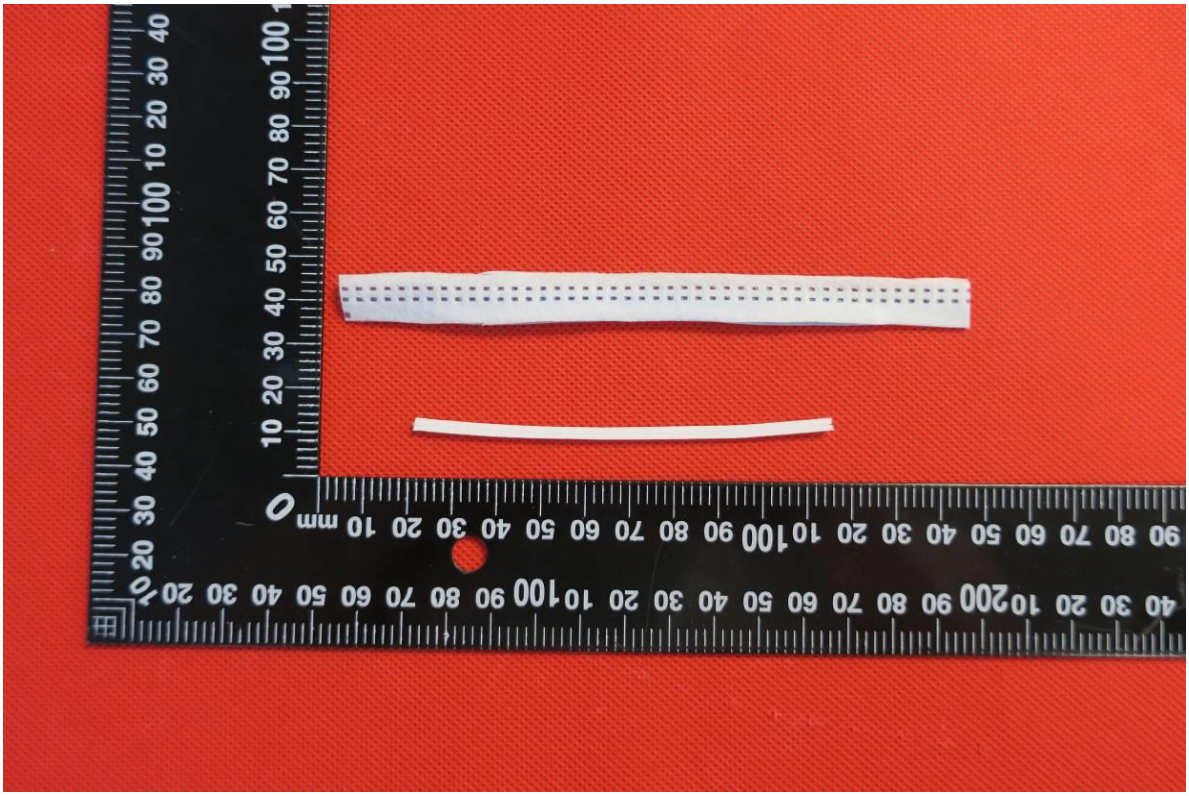

Figure 6 Inner view of mask – nose clip

Product: DISPOSABLE FACE MASK

Type Designation: Y6002

Figure 7 Front/ rear view of Package on box for mask

Figure 8 Top view of Package on box for mask

Product: DISPOSABLE FACE MASK

Type Designation: Y6002

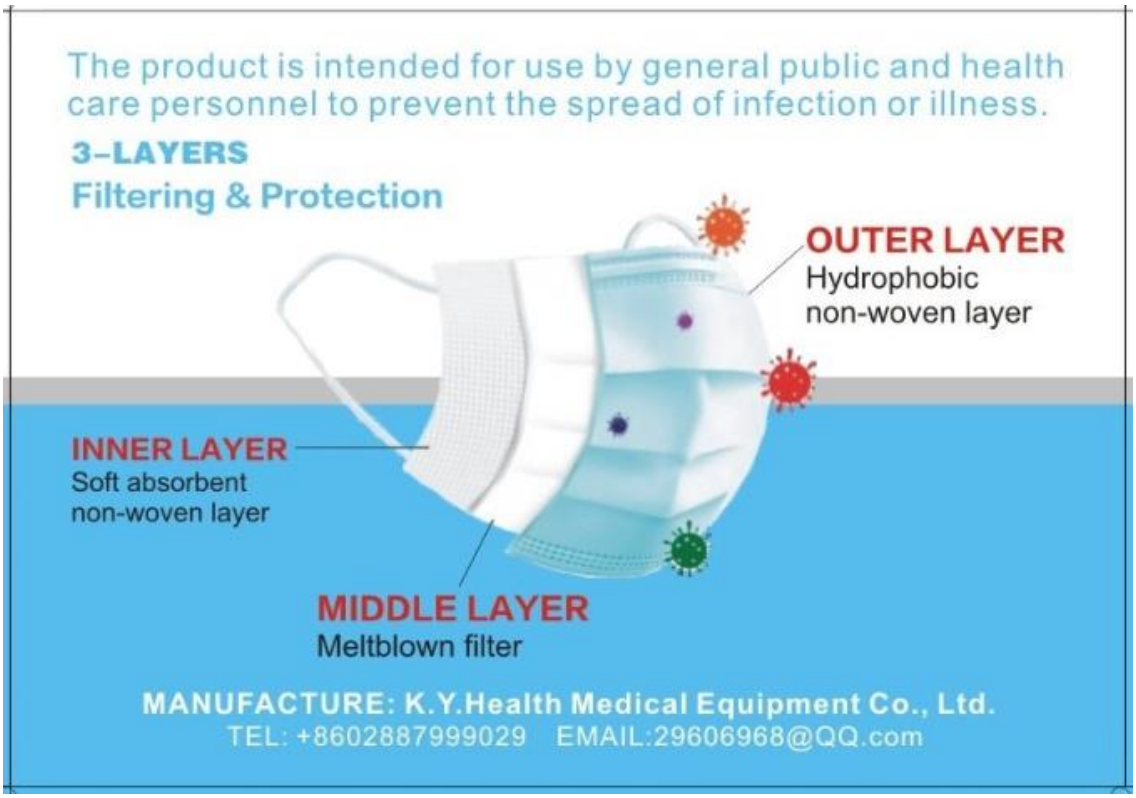

Figure 9 Side view of Package on box for mask

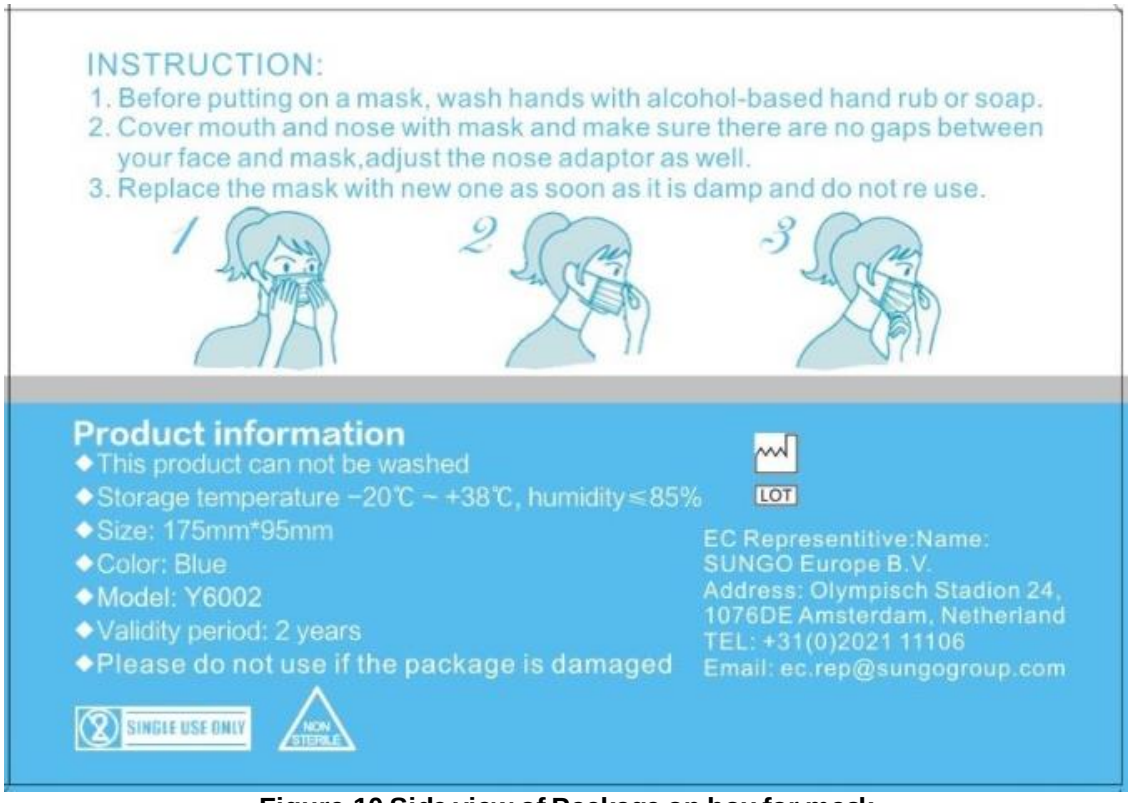

Figure 10 Side view of Package on box for mask

Product: DISPOSABLE FACE MASK

Type Designation: Y6002

QUALIFIED CERTIFICATE 合格证	
PRODUCT NAME 产品名称	DISPOSABLE FACE MASK
EXECUTION STANDARD 执行标准	EN14683-2019
主要成分 Main Component	65%无纺布，35%熔喷布 Non-woven Fabric, melt-blown fabric
PRODUCT MODEL 产品型号规格	Y6002 17.5cm*9.5cm
LOT NO. 批次号	20206118
MANUFACTURE DATE 生产日期	2020.04.20
PRODUCT QTY 产品数量	50 pcs
PERIOD OF VALIDITY 有效期	2 YEARS 2年
制造商：四川康源化医疗器械有限公司 K.Y.HEALTH MEDICAL EQUIPMENT CO., LTD.	
生产地址：四川省成都市郫都区望从东路777号 777 WANGCONGDONG RD, PIDU DISTRICT, CHENGDU, SICHUAN	

Figure 11 Qualified certificate in Package for mask

END OF THE PHOTO DOCUMENTATION