


Prüfbericht-Nr.: <i>Test Report No.:</i>	60410000 001	Auftrags-Nr.: <i>Order No.:</i>	168276721	Seite 1 von 12 Page 1 of 12
Kunden-Referenz-Nr.: <i>Client Reference No.:</i>	N/A	Auftragsdatum: <i>Order date:</i>	Aug. 05, 2020	
Auftraggeber: <i>Client:</i>	K.Y. Health Medical Equipment Co., Ltd. 777 Wangcongdong Rd, Pidun, Chengdu, Sichuan, 610000, P.R. China			
Prüfgegenstand: <i>Test item:</i>	DISPOSABLE FACE MASK			
Bezeichnung / Typ-Nr.: <i>Identification / Type No.:</i>	Y6006			
Auftrags-Inhalt: <i>Order content:</i>	Type test			
Prüfgrundlage: <i>Test specification:</i>	EN 14683:2019+AC:2019 except for clause 5.2.6			
Wareneingangsdatum: <i>Date of receipt:</i>	Aug. 07, 2020	See Attachment: Photo documentation for details.		
Prüfmuster-Nr.: <i>Test sample No.:</i>	20206166			
Prüfzeitraum: <i>Testing period:</i>	Aug. 10, 2020 to Aug. 20, 2020			
Ort der Prüfung: <i>Place of testing:</i>	See page 3			
Prüflaboratorium: <i>Testing laboratory:</i>	TÜV Rheinland (Shenzhen) Co., Ltd.			
Prüfergebnis*: <i>Test result*:</i>	Pass			
geprüft von: <i>tested by:</i>	Javen Ke	kontrolliert von: <i>authorized by:</i>	Angela Chen	
Datum: <i>Date:</i>	Aug. 21, 2020	Ausstellungsdatum: <i>Issue date:</i>	Aug. 21, 2020	
Stellung / Position:	Assistant Project Engineer	Stellung / Position:	Department Manager	
Sonstiges / Other:	<ul style="list-style-type: none"> - The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (5 pages). - The Biocompatibility (clause 5.2.6) is not evaluated in this test report. 			
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>	Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>			
* Legende:	1 = sehr gut P(ass) = entspricht o.g. Prüfgrundlage(n)	2 = gut F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	3 = befriedigend N/A = nicht anwendbar	4 = ausreichend N/T = nicht getestet
Legend:	1 = very good P(ass) = passed a.m. test specification(s)	2 = good F(ail) = failed a.m. test specification(s)	3 = satisfactory N/A = not applicable	4 = sufficient N/T = not tested
<p>Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i></p>				

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EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No.	60410000 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	
Manufacturer	Same as the applicant
Model/Type reference	Y6006
Classification	Type II

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (5 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 5.2.5 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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> 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 II. 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.

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 II	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		N/A
	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 II mask. See appended table 5.2.4	N/A
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 (cm ²)	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
2020616 6	1	153×152	63.6	28.3	1821	0	100.00	--
	2	153×152	63.6	28.3			100.00	--
	3	153×152	63.6	28.3			100.00	--
	4	153×152	63.6	28.3			99.84	--
	5	153×152	63.6	28.3			99.95	--
Supplementary information:								
1, Each specimen was conditioned at <u>21</u> °C and <u>85</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing.								
2, The side of the test specimen was facing towards the challenge aerosol: <u>inside of mask</u> .								

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/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks	
202061 66	1-1	33.1	34.2	8.0	--	
	1-2	34.5		8.0	--	
	1-3	39.0		8.0	--	
	1-4	35.5		8.0	--	
	1-5	28.8		8.0	--	
	2-1	34.5	34.7	8.0	--	
	2-2	38.7		8.0	--	
	2-3	34.0		8.0	--	
	2-4	31.0		8.0	--	
	2-5	35.2		8.0	--	
	3-1	29.2	32.9	8.0	--	
	3-2	37.2		8.0	--	
	3-3	32.8		8.0	--	
	3-4	34.4		8.0	--	
	3-5	30.7		8.0	--	
	4-1	30.9	34.4	8.0	--	
	4-2	32.9		8.0	--	
	4-3	31.8		8.0	--	
	4-4	28.2		8.0	--	
	4-5	33.3		8.0	--	
5-1	30.1	31.8	8.0	--		
5-2	34.5		8.0	--		
5-3	35.0		8.0	--		
5-4	28.9		8.0	--		
5-5	30.6		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			N/A
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
	11			
	12			
	13			
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EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

	29			
	30			
	31			
	32			

Supplementary information:

- 1, Each specimen was conditioned at ___°C and ___% relative humidity for ___h to bring them into equilibrium with atmosphere prior to testing.
- 2, The description of target area tested: _____.
- 3, Any technique used to enhance visual detection of synthetic blood: _____.
- 4, The temperature and relative humidity for testing: ___°C and ___%.
- 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	
20206166	1	3.0	<1	--	
	2	3.0	<1	--	
	3	2.9	<1	--	
	4	2.9	<1	--	
	5	3.0	<1	--	

Supplementary information:

The test is only related to the test sample provided by manufacturer.

End of EN 14683 test report

Product: DISPOSABLE FACE MASK

Type Designation: Y6006



Figure 1 View of packaging for mask in box
(Final marking of package box and qualified Label refer to Figure 6 to Figure 10 below)

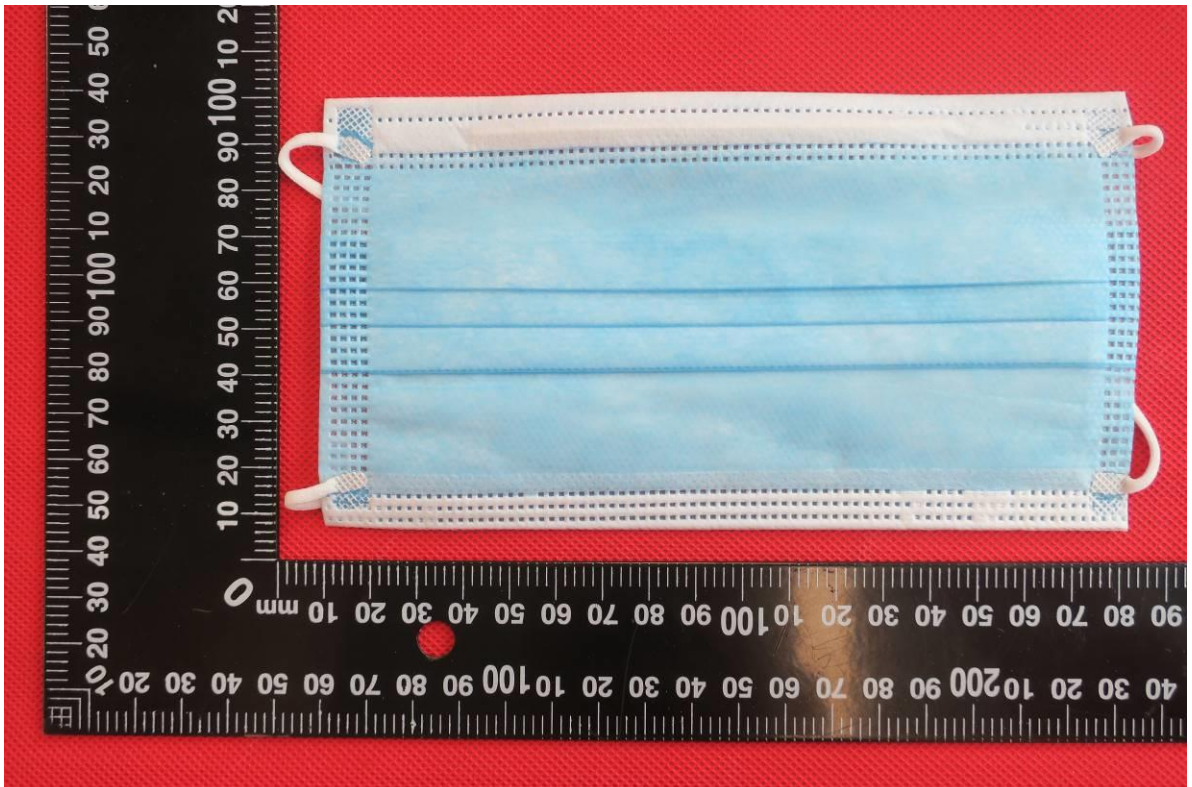


Figure 2 View of mask

Product: DISPOSABLE FACE MASK

Type Designation: Y6006

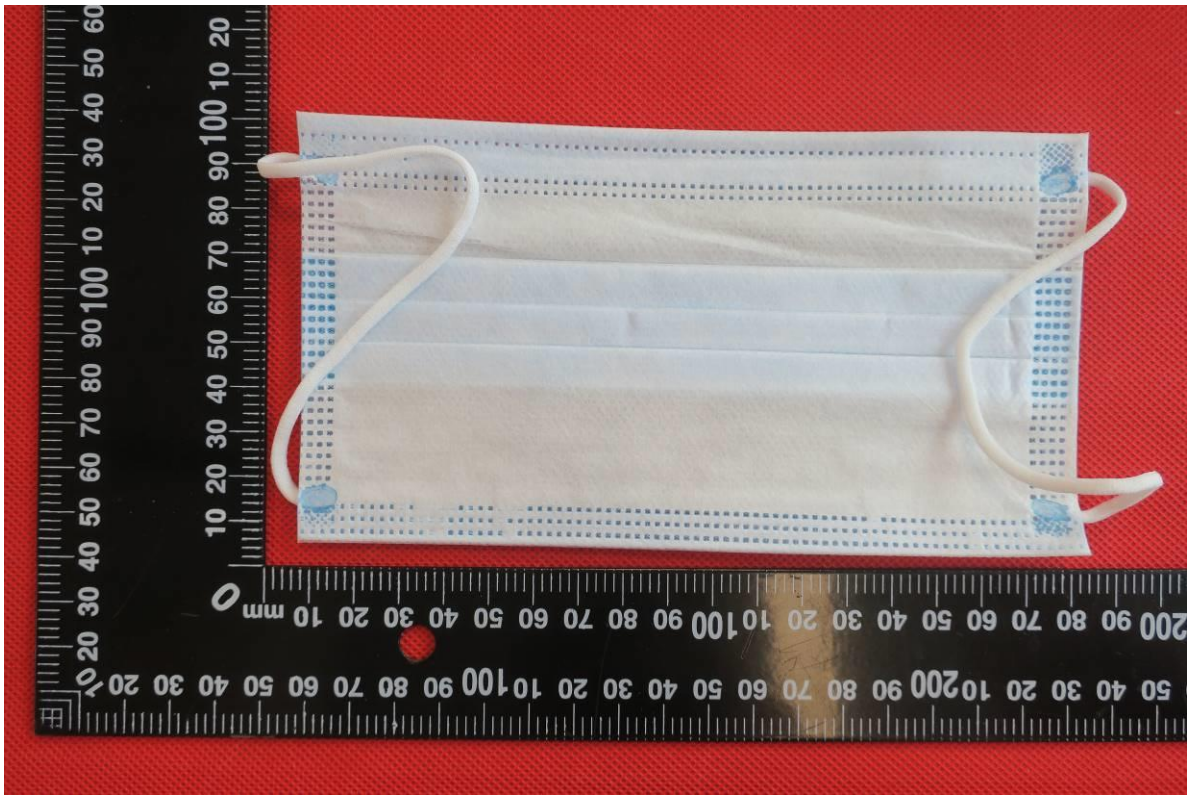


Figure 3 View of mask



Figure 4 Inner view of mask - layers

Product: DISPOSABLE FACE MASK

Type Designation: Y6006

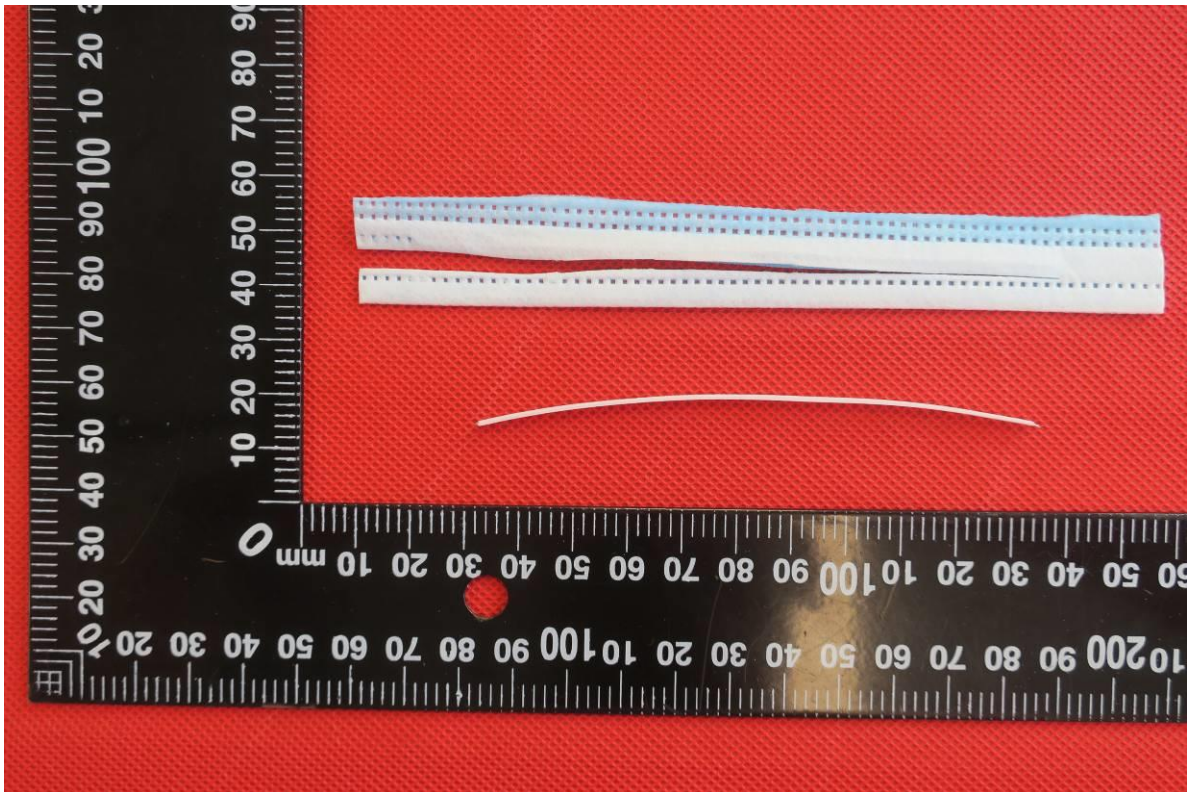


Figure 5 Inner view of mask – nose clip

合格证

PRODUCT NAME 产品名称	DISPOSABLE FACE MASK 康源化牌日常防护型口罩
EXECUTION STANDARD 执行标准	GB/T-32610-2016
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	Y6006 17.5cm*9.5cm
LOT NO. 批次号	20206166
MANUFACTURE DATE 生产日期	2020.07.25
PRODUCT QTY 产品数量	50
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 6 Qualified Label in Package for mask

Product: DISPOSABLE FACE MASK

Type Designation: Y6006



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: Y6006

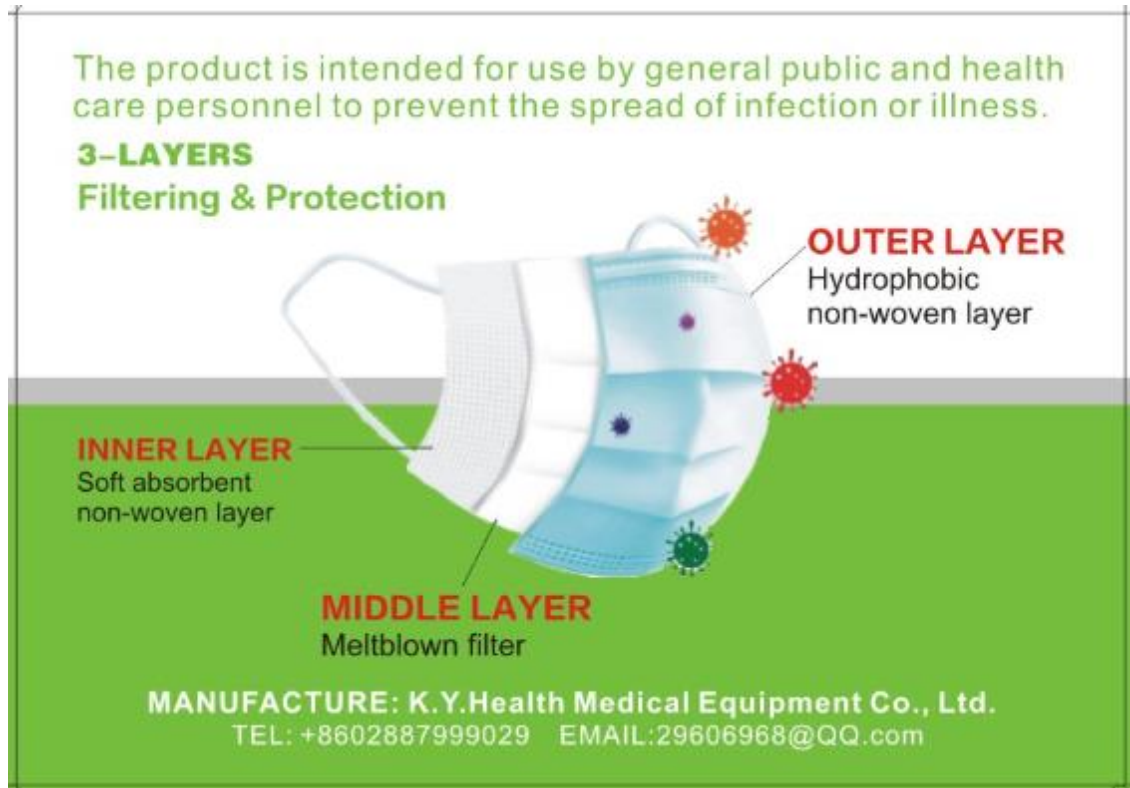


Figure 9 Side view of Package on box for mask



Figure 10 Side view of Package on box for mask

END OF THE PHOTO DOCUMENTATION