EC Declaration of Conformity

Manufacturer: Hunan EEXI Technology&Service Co.,Ltd.

Address: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

EU Authorised Representative:
Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Device Name: Disposable Surgical mask

Type: Type IIR

Classification : Class I
According to 93/42/EEC Annex IX, Rules 1, all non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. The Conformity Route is Annex VII EC declaration of conformity.

We, Hunan EEXI Technology&Service Co.,Ltd. herewith declare on our exclusive responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product.

Harmonized Standards:

All applicable harmonized Standards (Published in the Official Journal of the European Communities)
Please see Annex List.

Date of Issue:

10th May 2020

Signature:

Robbin Lin

General Manager

Prüfbericht-Nr.: *Test Report No.*:	**60377902 001**	**Auftrags-Nr.** *Order No.*:	**168264746**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.*:	N/A	**Auftragsdatum:** *Order date*:	May 13, 2020	
Auftraggeber: *Client*:	**Hunan EEXI Technology & Service Co., Ltd.** No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China			
Prüfgegenstand: *Test item*:	Surgical Face Mask (non-sterile)			
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	YX011			
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 14, 2020
Prüfmuster-Nr.: *Test sample No.*:	20200504
Prüfzeitraum: *Testing period*:	May 14, 2020 to May 28, 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 Lucy Jiang

Javen Ke / Assistant Project Engineer

May 28, 2020 Lucy Jiang / Assistant Project Engineer

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

kontrolliert von / *reviewed by*:

Angela Chen / Department Manager

May 28, 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. ..... :	**60377902 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 ..... :	**Hunan EEXI Technology & Service Co., Ltd.**
Address..... :	No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, 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..... :	Surgical Face Mask (non-sterile)
Trade Mark..... :	Inherent
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	YX011
Classification..... :	Type IIR

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.

Instruction

Article No.: YX011

Date of preparation of the manual: April 15, 2020
Manual version number: A3
Please refer to the instructions before use

Product name: Surgical Face Mask(non-sterile)
Type: Type IIR
Type and Specification: Flat earloop, 17.5*9.5cm
Production license No.: Hunan Food&Drug Administration permission 20200023
Registration No.: Hunan medical device registration permission 20202140288
Main material: 30%Meltblown non-woven, 70%Non-woven fabric
Standard Applied: EN 14683:2019+AC:2019 YY0469-2011
Intended Use:
The surgical face mask is single-use, disposable device, provided non-sterile, and intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
Structure and Components:
This mask is made by blank mask, nose piece and ear loops. The blank mask is made by three layers. The inner and outer layer are non-woven fabric, the middle layer is Melt-blown polypropylene.
Main performance:
1) Bacterial filtration efficiency: ≥98%;
2) Differential Pressure: < 60 Pa/cm² ;
3) Microbial cleanliness: ≤30 cfu/g;
4) Splash resistance pressure≥16kPa.
Introduction for use:
1) Open the package and remove a mask.
2) Hold the mask by the ear loops, confirm that the colored side is front and the nose piece is on the top of the mask. Hang the ear loops over your ears and mold the nose piece to the shape of your nose, pull the bottom of the mask over your mouth and chin.
Precautions:
1) Check the package is intact before use, conform the masks and date of manufacture on the external package, and use it before the expiry date.
2) If you are allergic to non-woven fabric, be cautious using this product.
3) After using the product, please dispose of it according to the requirements of the environments protection agency or related authorities.
4) This product is a disposable device. It is not recommended to the clean or reuse it. If you feel uncomfortable during use, please stop using it immediately or replace it with a new one.
Storage:
Store in a dry, well-ventilated, non-corrosive gas place, avoid high temperature.
Shelf life: 2 years.
Meaning of package symbols:

symbol	Explanation		
	Means "Do not reuse"		Means "Date of manufacture"
	Means "Do not use if package is damaged"	LOT	Means "Batch code"
	Means "Keep away from sunlight"		Means "Manufacturer"
	Means "Keep dry"		Means "Authorized representative in the European Community"

Batch code: refer to package
Date of manufacture: refer to package
Use by date: refer to package
Authorized representative in the European Community: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Manufacturer: Hunan EEXI Technology & Service Co.,LTD.
Address: No. 6 North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan, China.
TEL: +86-4000-333-088

See attachment for other information.

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 IIR.
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 IIR	**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.	The Surgical Face Masks are made of blank mask, nose clip and ear loops. The outer and inner layers of the mask are made of non-woven fabrics, and the middle layer is made of melt-blown polypropylene.	**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**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	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**
	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.	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 $\leqslant$ 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**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	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 page 4 and attachment.	**P**
	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**
20200504	**1**	**162×150**	**63.6**	**28.3**	**1763**	**0**	**99.72%**	**--**
	2	**161×150**	**63.6**	**28.3**			**99.66%**	**--**
	3	**161×151**	**63.6**	**28.3**			**99.78%**	**--**
	4	**161×151**	**63.6**	**28.3**			**99.68%**	**--**
	5	**161×151**	**63.6**	**28.3**			**99.66%**	**--**

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: the inside of the test specimen.

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**
20200504	1-1	23.7	24.9	8.0	--
	1-2	25.2		8.0	--
	1-3	28.3		8.0	--
	1-4	23.1		8.0	--
	1-5	24.4		8.0	--
	2-1	17.7	24.3	8.0	--
	2-2	26.7		8.0	--
	2-3	26.3		8.0	--
	2-4	25.2		8.0	--
	2-5	25.7		8.0	--
	3-1	27.8	24.6	8.0	--
	3-2	26.4		8.0	--
	3-3	21.9		8.0	--
	3-4	22.8		8.0	--
	3-5	24.3		8.0	--
	4-1	22.6	25.5	8.0	--
	4-2	29.2		8.0	--
	4-3	27.1		8.0	--
	4-4	24.3		8.0	--
	4-5	24.2		8.0	--
	5-1	14.4	21.0	8.0	--
	5-2	21.8		8.0	--
	5-3	24.5		8.0	--
	5-4	22.1		8.0	--
	5-5	22.3		8.0	--

Supplementary information:
Each specimen was conditioned at 21 °C and 85 % relative humidity for 16 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**
20200504	**1**	**See clause 5.1.1**	**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**
20200504	**1**	**2.9**	**<1**	**--**
	2	**2.8**	**<1**	**--**
	3	**3.0**	**<1**	**--**
	4	**3.0**	**<1**	**--**
	5	**2.9**	**<1**	**--**

Supplementary information:

End of EN 14683 test report

Product: Surgical Face Mask (non-sterile)

Type Designation: YX011

Figure 1 Front / Back view of packaging box
(The marking shown above will be replaced by the marking in Figure 4 in final packaging bag)

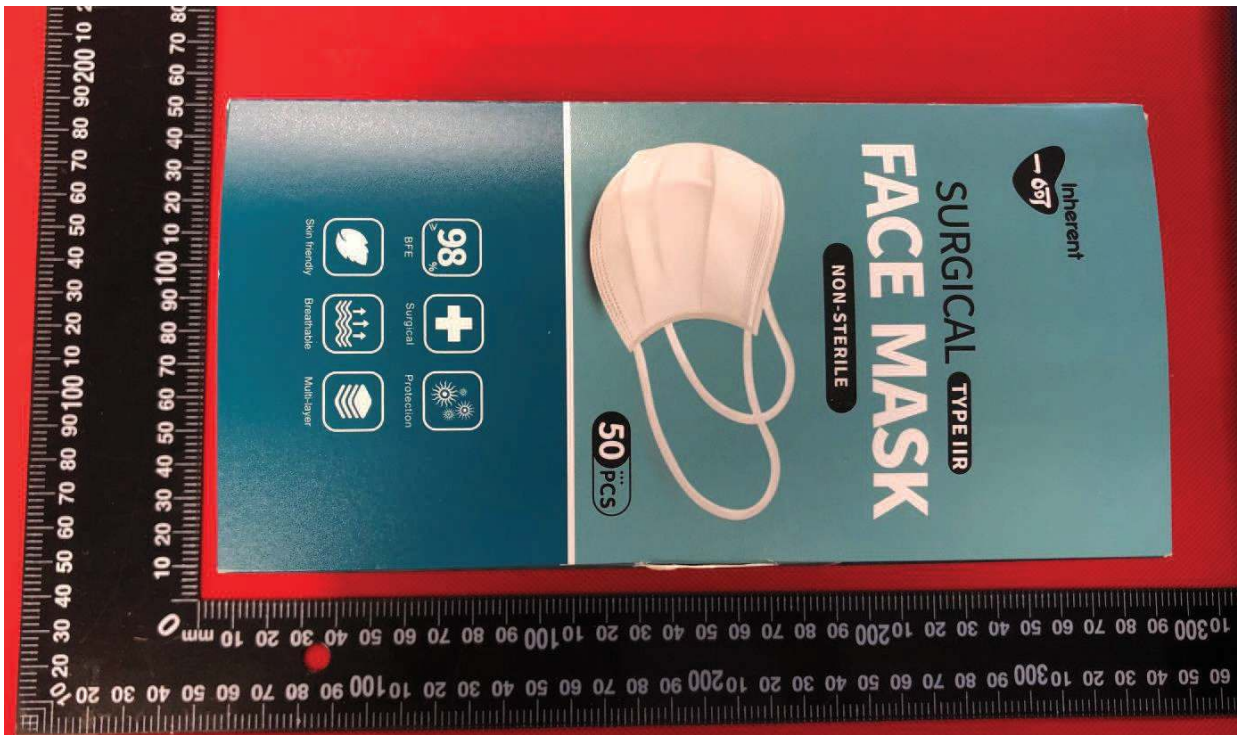

Figure 2 Top view of packaging box
(The marking shown above will be replaced by the marking in Figure 5 in final packaging bag)

Product: Surgical Face Mask (non-sterile)

Type Designation: YX011

Figure 3 Side view of packaging box
(The marking shown above will be replaced by the marking in Figure 6 in final packaging bag)

Figure 4 Front / Back view of packaging box

Product: Surgical Face Mask (non-sterile)

Type Designation: YX011

Figure 5 Top view of packaging box

Figure 6 Side view of packaging box

Product: Surgical Face Mask (non-sterile)

Type Designation: YX011

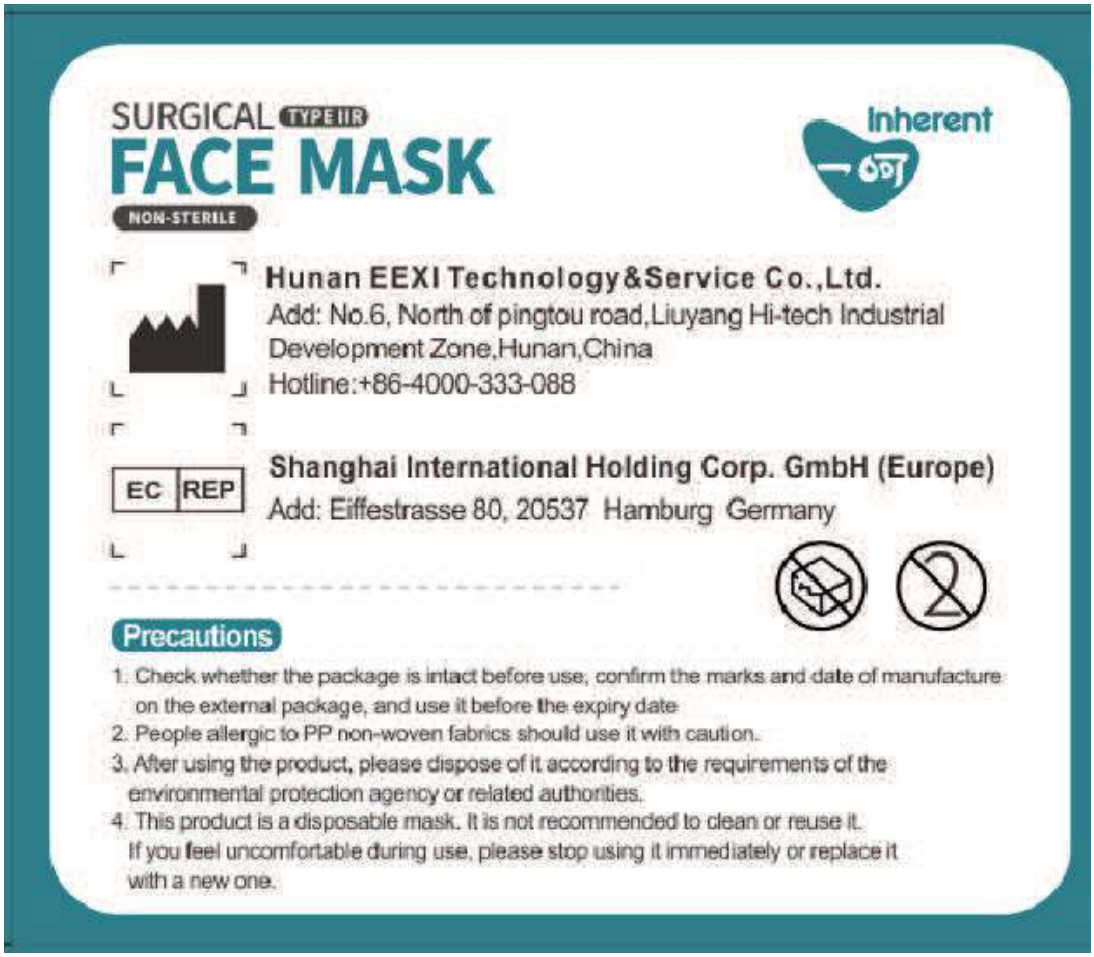

Figure 7 Side view of packaging box

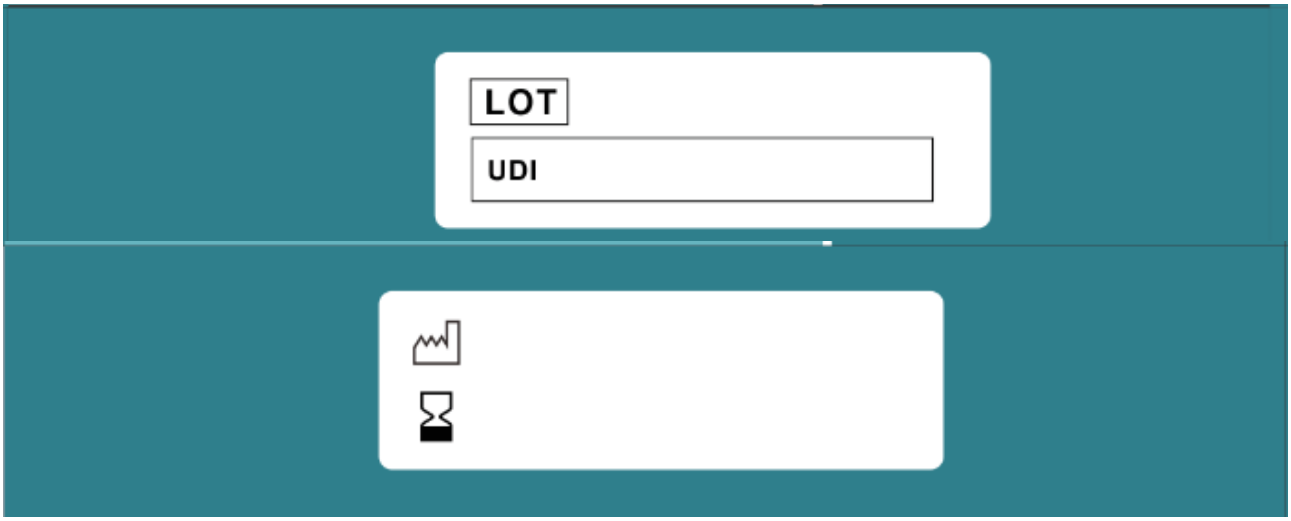

Figure 8 Bottom view of packaging box

Product: Surgical Face Mask (non-sterile)

Type Designation: YX011

Figure 9 View of packaging bag

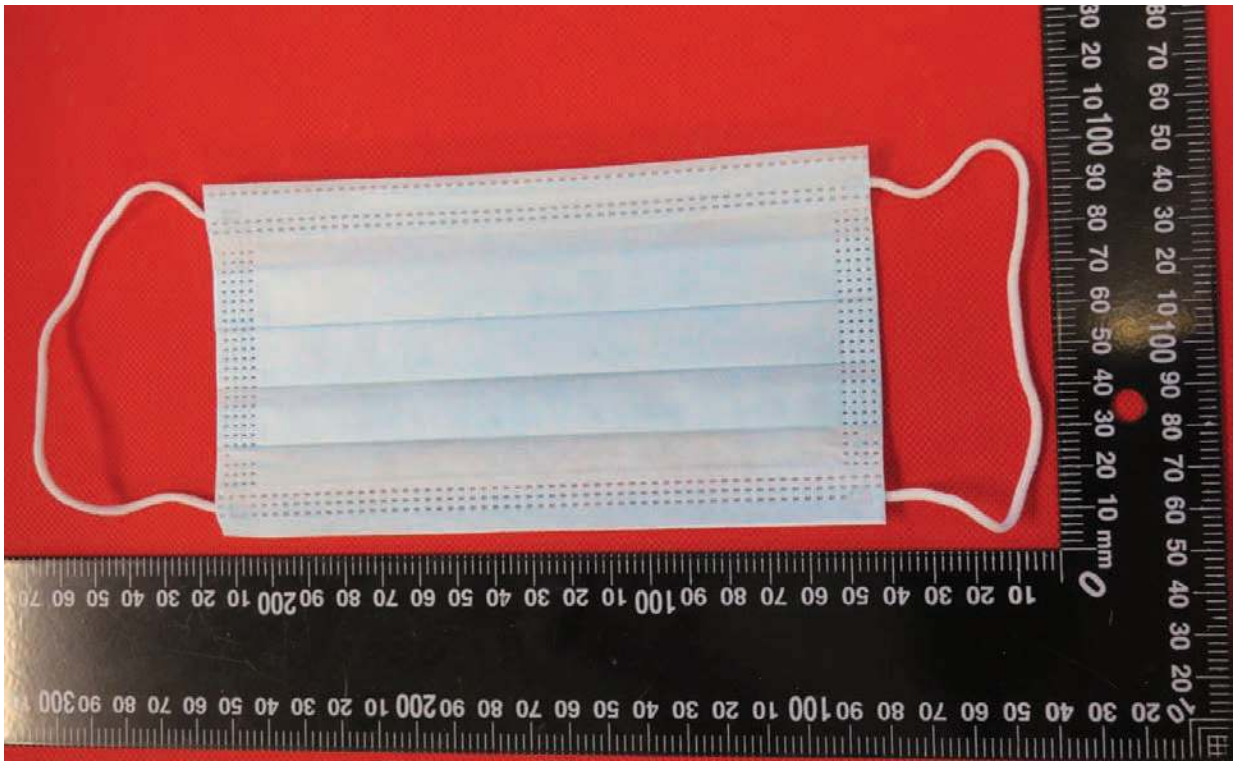

Figure 10 View of face mask

Product: Surgical Face Mask (non-sterile)

Type Designation: YX011

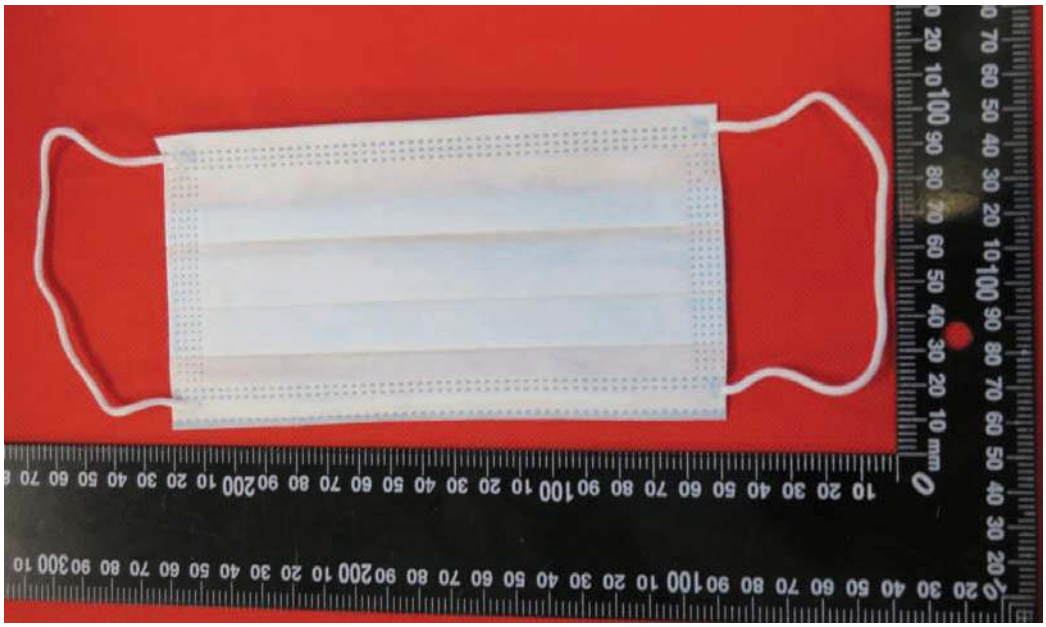

Figure 11 View of face mask

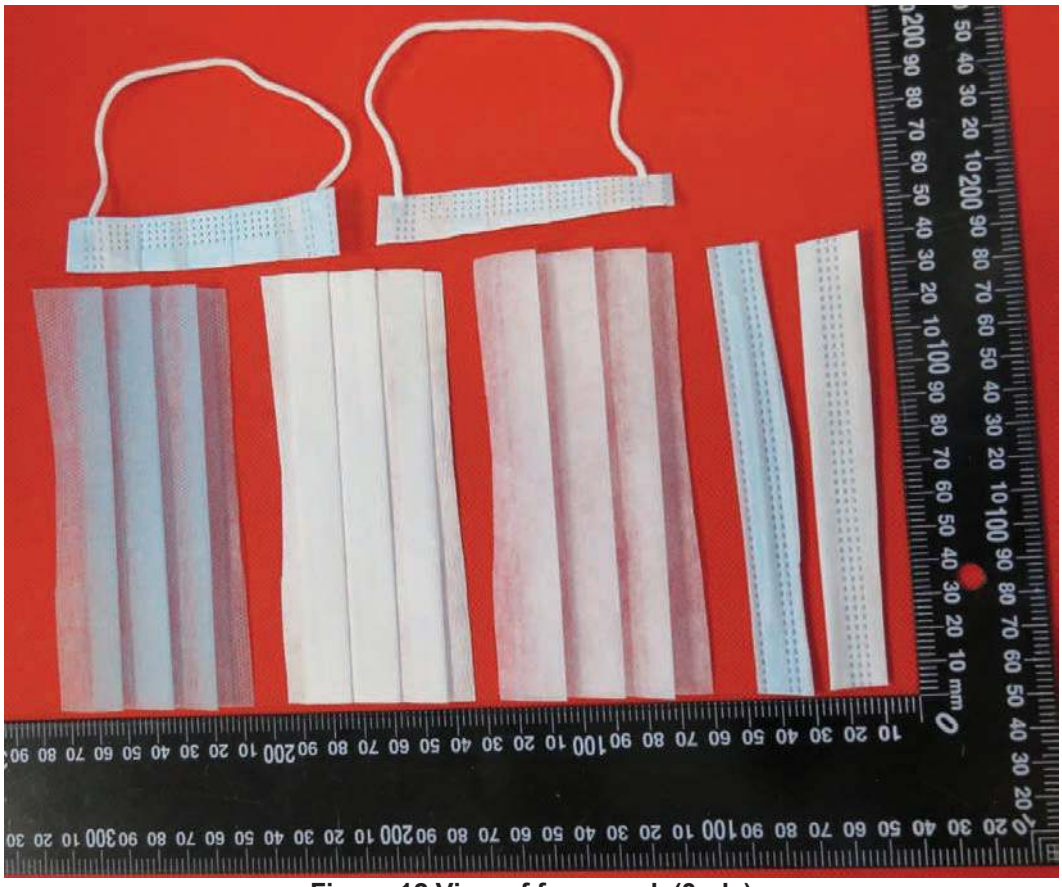

Figure 12 View of face mask (3-ply)

END OF THE PHOTO DOCUMENTATION