

Datum:	20/05/2021	PRP 13 PRODUCTFILES	I-HACCP	
			Map	2
Versie:	2			
Opgesteld door: Q-team	Candy Ott		Controle door: QA	

Reference:	9001984
Supplier reference:	
Description:	Non-Woven mask 50x + elastics blue 3-layer Medical Type IIR
Barcode CU:	5404017206649
Barcode CARTON:	5404017206656

Picture:



Item specifications:

Non-Woven mask 50x + elastics blue 3-layer **Medical Type IIR**

Color	Blue
Designs	Nose bar : aluminium plastic, earloop : polyester spandex
Kind of mouth mask	3 layers
Fabric	Non woven
Type of binding	Ear elastics
Kind of mask	Mouth mask
Outer sorting	40x 50pc

Artwork of box



19x10x7

Packaging Outer

Quantity	40
Kind of outer	BROWN CARTON
EAN	5404017206656
Dimensions	33x23x27,5cm





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel,
The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041: 2008+A1: 2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683: 2019+AC: 2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-RF-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Sword Xiantao Disposable Protective Products Factory
Address: Liukou Industrial Zone, Xiantao City, 433000, Hubei Province, China
SRN: CN-MF-000009766

Product Information

Name: Surgical Masks
Model: 17.5cm* 9.5cm, 14.5cm* 9.0cm, customizable
GMDN: 66199
Basic UDI-DI: 697163167SM2Z
Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2022.9.15

Position: GM

Place: Hubei / China





Belscan Continental bv
Industriepark E17/3202 Stokkelaar 4
9160 LOKEREN

Your notice of	Your reference	our reference YR2287_2023	date 5 July 2023
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Certification report

1. Description of the tested article:

Mask reference : Ref. 9001984
Surgical Masks Class I (Medical Type IIR)
UDI-DI : 697163167SM2Z

2. Executed tests:

EN 14683 – Annex B (2019) + AC (2019)	} According to EN 14683 (2019) + AC (2019)
EN 14683 – Annex C (2019) + AC (2019)	
ISO 22609 (2004)	
EN 14683 – Paragraph 5.2.5 (2019) + AC (2019)	

Detailed results can be found in:
Analysis report Nr. 23.03324.02 dated 5 July 2023.

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, the uncertainty on the test results is not taken into account. Compliance rules followed are those mentioned in the applicable standard. In case of unclear rules all individual results must meet the specifications.

Centexbel is authorised by decree of the Ministry of Employment and Labour AV/OA235/ST, dated 25/5/94 and identified under the number 0493 by the European Committee.

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3. Conclusions :

Table 1 : Performance requirements for **medical face masks**

Test	Type I ^a	Type II	Type IIR
Bacterial filtration efficiency - BFE (%)	≥ 95	≥ 98	≥ 98
Differential pressure Delta P (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16.0 ^b
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

^b Corresponds to the pressure for which the medical face mask achieves an acceptable quality limit (AQL) of 4,0 %. This AQL is met for a single sampling plan when 29 or more of the 32 tested specimens show “pass” results.

Table 2 : Summary of the results obtained on the tested mask

MASK REFERENCE	CHARACTERISTIC	UNIT	RESULTS				
			>99.9	>99.9	>99.9	>99.9	>99.9
Ref. 9001984 Surgical Masks Class I (Medical Type IIR) - UDI-DI: 697163167SM2Z	BFE	%	>99.9	>99.9	>99.9	>99.9	>99.9
	Delta P	Pa/cm ²	37.0	40.3	37.6	38.9	40.8
	Microbial cleanliness	cfu/g	< 11	< 3	11	< 3	< 3
	Splash resistance pressure	Number of “Pass” results at 16 kPa	32/32				

According to EN 14683 (2019) + AC (2019), the **Ref. 9001984 Surgical Masks Class I (Medical Type IIR) - UDI-DI: 697163167SM2Z**, fulfils all the requirements of the **TYPE IIR** medical face masks.

Certification report No. YR2287_2023 is valid until 30/06/2028.

Yvette Register - Head of Microbiological Laboratory
p.p. Stijn Devaere, Ph D - Director of Services