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Management System
ISO 9001:2015
ISO 14001:2004
TÜVRheinland CERTIFIED
www.tuv.com ID 9105027172

Medical mask EP Hygitex Mask 2

Technical Data Sheet

Hydrophobic layer repels water, blood and other fluids

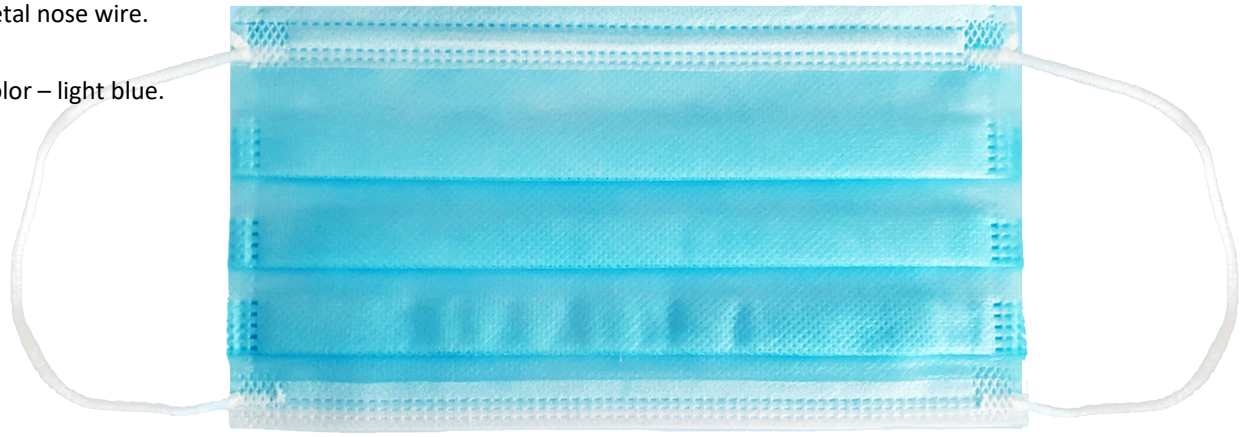
Filter layer stops microbes and other particles from entering or exiting mask.

Hydrophilic layer is absorbent and keeps mask dry, skin friendly and allergy free.

Elastic ear-loops.

Metal nose wire.

Color – light blue.



				Non-woven spunbond polypropylene 25 g/m²	Non-woven meltblown polypropylene 20 g/m²	Product
Parameter	**Standard**	**Direction**	**Unit**	**Value**		
Grammage	ISO 9073-1	–	g/m²	25	20	70
Tensile Strength	ISO 9073-3	MD	N/50 mm	37	7	50
		TD		30	7	30
Elongation at Break		MD	%	90	40	80
		TD		120	70	100
Tear Resistance	ISO 9073-4	MD	N	24	–	30
		TD		15	–	20
Impact Energy	ASTM D3420	–	J	0.3	0.1	0.4
Fiber Size	EP-TN-1018		µm	23	3	–
Fabric Thickness	EP-TN-1020		mm	0.1	0.2	0.3
Bacterial Filtration Efficiancy (BFE)*	EN 14683		%	–	–	98
Differential Pressure (ΔP)*			Pa/cm²	–	–	31

*– Tests were carried out in CENTEXBEL Laboratory, accredited by Belgian Accreditation Council.

Date
2 May 2020

Prepared by.....
E. Penchev – Head of R&D Laboratory

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Bulgarie

Your notice of	**Your reference**	**Date**
14-04-2020		02-05-2020

Analysis Report 20.02144.01

Required tests :

EN 14683 (2019) + AC (2019)	**EN 14683 - annex B (2019) + AC (2019)**	**Bacterial filtration efficiency**
EN 14683 (2019) + AC (2019)	**EN 14683 - annex C (2019) + AC (2019)**	**Medical face masks - Breathability (differential pressure)**

Identification number	Information given by the client	Date of receipt
T2008046	EP Hygitex Mask 2 (batch 1)	14-04-2020

Sylvie Niessen
Order responsible

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Reference: **T2008046 - EP Hygitex Mask 2 (batch 1)**

Bacterial filtration efficiency

Date of ending the test	27-04-2020
Standard used	EN 14683 - annex B (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	**Outer layer** : Spunbond nonwoven PP 25 g/m² - Color blue **Middle layer** : Meltblown nonwoven PP 22 g/m² - Color white **Inner layer** : Spunbond nonwoven PP 25 g/m² - Color white
Number of tested masks :	3
BFE Area tested :	± 49 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	1700 - 3000 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge
Deviation from the standard	Test result based on 3 instead of 5 samples

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \; X \; 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested mask

# Mask	B (%)
1	98.7
2	99.2
3	98.7

Mean particle size of the bacterial challenge aerosol : 2.7 µm

Controls

Mean positive controls 2407 CFU
Negative control < 1 CFU

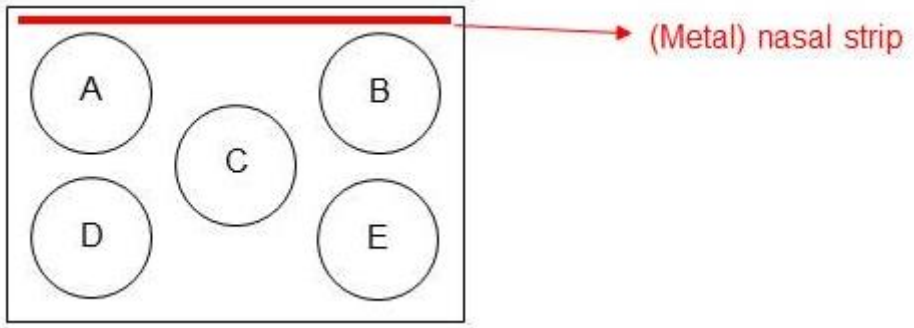
This test report is valid for products used in relation to the current Covid-19 health crisis and for products which are not entering the regular distribution channels. Cfr Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat"

Reference: **T2008046 - EP Hygitex Mask 2 (batch 1)**

Medical face masks - Breathability (differential pressure)

Date of ending the test	20-04-2020
Standard used	EN 14683 - annex C (2019) + AC (2019)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Blue/white masks folded differently - No elastic for the ears.
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results **Δ P**

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	35.4	29.9	32.4	28.5	26.7
Area B	29.9	35.4	36.9	34.4	30.8
Area C	32.4	41.6	32.4	25.9	34.4
Area D	27.7	27.9	31.4	27.1	28.5
Area E	30.8	30.8	31.0	27.7	24.9
Average ΔP (Pa/cm²)	**31.2**	**33.1**	**32.8**	**28.7**	**29.1**