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Your notice of
15-07-2020

Your reference

Date
31-07-2020

Analysis Report 20.04481.02

Translation of analysis report 20.04481.01, made on 31-07-2020

Required tests :

EN 14683 (2019) + AC
(2019)

ISO 22609 (2004)

Medical face masks - Splash Test

Identification number	Information given by the client	Date of receipt
T2015775	Ultramask - The Medical Facemasks	15-07-2020



Sylvie Niessen
Order responsible

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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, we did not take into account the uncertainty on the test results.



Reference: T2015775 - Ultramask - The Medical Facemasks

Medical face masks - Splash Test

Date of ending the test	29-07-2020
Standard used	ISO 22609 (2004)
Product standard	EN 14683 (2019) + AC (2019)
Mask description	Ultramask - The Medical Facemasks
Number of tested masks :	32
Blood surface tension	42 ± 2 dynes/cm
Volume of the delivered blood	2 ml
Distance "canula-mask"	30 ± 1 cm
Side of the mask "impacted"	Outer side
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Results

Blood pressure tested 16.0 kPa

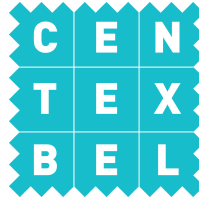
Controls

Blood visualisation on the mask	OK
Calibration procedure	OK
Control of the blood volume delivered (2 ml)	
- before the test :	OK
- after 16 masks :	OK
- after 32 masks :	OK



Results obtained on the set of masks

# Mask	Results : pass / fail
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
29	Pass
30	Pass
31	Pass
32	Pass



Summary P = 16.0 kPa

Number of "Pass" masks	Number of "Fail" masks
32	0

Pass = no blood detected on the observed side

Fail = blood detected on the observed side

In agreement with the customer the number of tested mask has been determined based on a single sampling plan providing an AQL of 4 % (acceptable quality limit).

If 29 masks or more over 32 obtain a "Pass" result the 4% AQL is reached.

Note :

The performance requirements for medical face masks according to EN 14683 (2019) + AC (2019) is :

Test	Type I	Type II	Type IIR
<i>Splash resistance pressure (kPa)</i>	Not required	Not required	≥ 16