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Date

2020-05-26

Reference

2F012159-2 Rev1

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Sample ID 2P02865-29-2

Gibson Lifestyle AB

Att Erik Gibson

Erik Dahlbergsgatan 18

115 32 Stockholm

Splash resistance and breathability testing of protective face masks

Assignment

Evaluate splash resistance and breathability resistance of 32 + 5 face protective face masks following the guidelines of SS-EN 14683:2019 sections 5.2.3 and 5.2.4. The test is intended to identify products that are unlikely to fulfil all the requirements in 14683:2019.

Test items

The following face masks were provided by the customer:

Table 1 Test items provided by the customer

Item nr	Description
1-37	Esound Medical Surgical Mask, YY0469-2011, 200303616

Methods

Testing procedure for splash resistance was according SS-EN 14683:2019 section 5.2.4, which further refers to ISO 22609:2004:

The masks were pre-conditioned at room temperature and 85% relative humidity for at least 4 hours. After removed from conditioning chamber, the masks were mounted on a mask stand and exposed to a jet of 2 ml synthetic blood ejected at Medium pressure (see Table 2).

Table 2 Blood splash resistance test conditions

Ejection pressure	Ejection pressure (kPa)	Blood stream velocity (cm/s)
Low	10.6	450
Medium	16.0	550
High	21.3	635

After 10 seconds from the exposure, it was observed if the blood penetrated to an opposite side of the mask. The result was ranked “passed” if the blood remained on the impact side; or “failed” if the blood penetrated or wetted the material on the opposite side of the mask.

The blood jet was aimed at the centre of the mask.

No targeting plate was used following section 7.2 of ISO 22609:2004.

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Synthetic blood complying with the standard specifications (corrected surface tension 42 ± 2 mN/m, Lot # 419201) was purchased from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906 USA.

The testing was performed at room temperature (21 deg. C) and 30% relative humidity within 1 minute after the mask was removed from the conditioning chamber.

SS-EN 14683 requires that mask Type IIR pass at least Medium pressure test for 29 out of 32 pcs as minimum, corresponding to AQL 4%. A test with smaller number of samples gives an indication if the products will fail a full test. If four or more masks fail the quick test, it is not possible to pass the complete test requiring 32 pcs.

Testing procedure for breathability was according to SS-EN 14683:2019 section 5.2.3:

Preconditioned masks were clamped between two chambers of 25 mm inner diameter and air flow of 8L/min was created by a vacuum across the clamped mask area. The created pressure difference across the mask was recorded.

The SS-EN 14683 requires differential pressure to be less than 40 Pa/cm² for Type I and II masks and less than 60 Pa/cm² for Type IIR masks. For a full compliance with the standard SS-EN 14683:2019, minimum five masks should be tested, each on preferably five representative areas. If one specimen cannot provide 5 test areas of 25 mm diameter, the number of test areas retrieved should be representative for the entire mask.

Results

The splash resistance results are summarised in Table 3 and breathability resistance results are provided in Table 4. Excluding the requirements for statistics, the tested masks passed the splash resistance requirements for Type IIR masks (31 pass, 1 fail). The tested masks have passed breathability requirements for Type I, II and IIR masks.

Table 3. Blood splash resistance results

Item nr	Low pressure (10.6 kPa)	Medium pressure (16.0 kPa)	High pressure (21.3 kPa)
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	-	Fail	-
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	-
Total passed	-	31	-
Total failed	-	1	-

Table 4 Breathability resistance results

Item nr	Test area nr	Differential pressure per 25 mm diam. orifice (Pa)	Differential pressure per sq. cm (Pa/cm ²)	Mean per item (Pa/cm ²)	SD per item (Pa/cm ²)
33	1	95	19	23	3
	2	122	25		
	3	113	23		
	4	126	26		
	5	99	20		
34	1	109	22	23	1
	2	114	23		
	3	122	25		
	4	107	22		
	5	109	22		
35	1	118	24	23	1
	2	119	24		
	3	122	25		
	4	106	22		
	5	110	22		
36	1	117	24	23	1
	2	120	24		
	3	115	23		
	4	105	21		
	5	108	22		
37	1	97	20	21	2
	2	114	23		
	3	105	21		
	4	95	19		
	5	113	23		
Mean			23	23	
SD			2	1	

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Revision: Updated assignment. This report replaces the previous one issued 2020-05-26.