

Technical Construction File

File No: QA2020032821 2020-03-25

According to
PPE Directive (EU) 2016/425

Related to the

Disposable Protective Mask FFP2

Model: 170*95mm

Summary of assessment*

Clause		Assessment (see Key)	
		Model:	
		170*95mm	
7.4	Packaging	P	
7.5	Material	P	
7.6	Cleaning and disinfecting		
7.7	Practical performance	P	
7.8	Finish of parts	P	
7.9.1	Total inward leakage	P	
7.9.2	Penetration of filter material: Sodium chloride	P	
7.9.2	Penetration of filter material: Paraffin oil	P	
7.10	Compatibility with skin		
7.11	Flammability	P	
7.12	Carbon dioxide content of the inhalation air	P	
7.13	Head harness	P	
7.14	Field of vision	P	
7.15	Exhalation valve(s)	P	
7.16	Breathing resistance	P	
7.17	Clogging		
7.18	Demountable parts	P	
9	Marking		
10	Information to be supplied by the manufacturer		

	Shading shows the clauses requested. Any other clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "Result details" section for more information.
Fail	Requirement not satisfied. Refer to the "Result details" section for more
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those specimens which were tested and are the subject of this file.

Product characteristics

Property	Characteristic
Model	170*95mm
Classification claimed	FFP2 NR
Exhalation valve(s)	N

Submission details

Product	Quantity	Date received	QA specimen no. (1F0171 +)
170*95mm	120	20 March 2020	101 to 163 and 201 to 263

Procedures

The specimens detailed within the submissions above were used for the tests covered by this file.

Testing was performed in accordance with BS EN 149 : 2001 incorporating corrigendum No. 1 (July 2002) and amendment A1 (March 2009), unless otherwise specified below.

Result details

7.4	Packaging Model: 170*95mm	
	The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	NAs
	The masks were packaged in sealed plastic bags which gave some protection against mechanical damage or contamination before use.	Pass

7.5	Material Model: 170*95mm	
	The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	<u>Pass</u>
	The masks were packaged in sealed plastic bags which gave some protection against mechanical damage or contamination before use.	<u>NAs</u>
	Specimens 120 to 125 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.	<u>Pass</u>
	Specimens 106 to 110, 117 to 119, 126 to 131, 133, 139, 140, 146, 147, 156 to 158 and 161 to 163 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.	<u>Pass</u>
	The effects of filter media release were not assessed. Manufacturer to certify.	<u>NAs</u>

EC DECLARATION OF CONFORMITY



According to the following EC Directives,

Personal protective equipment Directive: (EU) 2016/425

Applicant Name:

Manufacturers Name:

Product name: Disposable respirator mask FFP2

Type(s): 170*95mm

Provided that it is used and maintained in accordance with the general accepted codes of good practice and the recommendations of the instructions manual, meet the essential safety and health requirements of the Personal protective equipment Directive. For the most specific risks of this equipment, safety and compliance with the essential requirements of the Directive has been based on elements of :

EN 149:2001+A1:2009	Respiratory protective devices. Filtering half masks to protect against particles.
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The company named above will keep on file for review the following technical documentation:

Operating and maintenance instructions:

Description of measures designed to ensure conformity

Other technical documentation, e.g. quality assurance measures for design and production

ATTENTION

The attention of the specified, purchase, installer, or user is drawn to special measures and limitations to use which must be observed when the product is taken into service to maintain compliance with the above directives, details of these special measures and limitations to use are available on request, and are also contained in the product manuals.

Date: 2020-03-25
Signature: 
Qualification: General Manager



7.7 Practical performance**Specimen and subject details**

Specime	Subject
1	VE
1	KDS

No adverse comments were made following testing.

Specimen and subject details

Specimen	Subject
248 + 348	EM
249 + 349	AGI

Specimen	Subject
250 + 350	PU
251 + 351	CKN

No adverse comments were made following testing.

7.8	Finish of parts	
	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs	Pass

7.9.1 Total inward leakage (%)

Subject	Specimen	Cond.	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
RW	101	A.R.	1.98	2.95	2.35	1.60	1.09	1.99
ED	102	A.R.	0.15	0.16	0.21	0.28	0.11	0.18
AH	103	A.R.	0.40	0.65	2.09	1.48	0.40	1.00
PBU	104	A.R.	4.76	2.69	2.92	2.42	2.82	3.12
CKN	105	A.R.	1.00	1.28	1.34	1.06	1.11	1.16
VE	106	T.C.	0.80	1.00	0.54	0.42	0.38	0.63
KDS	107	T.C.	0.90	1.42	0.34	0.93	1.74	1.06
INH	108	T.C.	0.80	0.73	0.75	0.70	0.74	0.74
SAH	109	T.C.	0.60	0.89	1.46	0.54	0.30	0.75
GW	110	T.C.	0.62	0.52	0.32	1.48	0.53	0.69
Maximum permitted			11					8

All 50 individual exercise results were not greater than 11% Pass

All 10 individual wearer arithmetic means were not greater than 8% Pass

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth	Mouth Width (mm)
170*95mm	170	95	/	/

7.9.2 Penetration of filter material

Sodium chloride: Pass

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max.during exposure
111	A.R.	0.09	
112		0.15	
113		0.16	
120	S.W.	0.16	
121		0.27	
122		0.22	
126	M.S. + T.C.	0.35	0.35
127		0.28	0.28
128		0.27	0.27
Maximum permitted		6.0	

Paraffin oil:

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
114	A.R.	0.71	
115		0.77	
116		0.78	
123	S.W.	2.37	
124		1.03	
125		1.59	
129	M.S. + T.C.	0.78	1.47
130		1.68	3.16
131		2.36	4.60
Maximum permitted		6.0	

7.10	Compatibility with skin	
	No problems were encountered during practical performance testing.	Pass
	No problems were encountered during total inward leakage testing.	Pass

7.11	Flammability	
	Specimens 144 and 145 (A.R.) and 146 and 147 (T.C.) were tested. specimens ignited.	Pass

7.12 Carbon dioxide content of the inhalation air

Specimen	CO2 (%)
135	0.66
136	0.72
137	0.60
Maximum permitted	1.0

7.13	Flammability	
	The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during practical performance and total inward leakage testing	<u>Pass</u>
	The product satisfied the total inward leakage requirements. See 7.9.1 for results.	<u>Pass</u>
7.14	Field of vision	
	There were no adverse comments following practical performance tests.	<u>Pass</u>

7.15 Exhalation valve

N/A

7.16 Breathing resistance

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
111	A.R.	0.52	1.67	2
112		0.31	1.44	2
113		0.38	1.38	2
117	T.C.	0.55	1.71	2
118		0.47	1.64	2
119		0.36	1.47	2
120	S.W.	0.46	1.62	1
121		0.45	1.59	2
122		0.42	1.60	2
138	A.R. + F.C.	0.46	1.62	2
139	T.C. + F.C.	0.45	1.67	2
140		0.44	1.55	1
Maximum permitted		0.7	2.4	3

7.18	Demountable parts	
	The following parts were demountable: the exhalation valve cover was readily connected by hand.	NAs

Estimates of the uncertainty of measurement

Clause	Test	Uncertainty
7.4	Packaging	Not applicable
7.5	Material	See Note 1
7.6	Cleaning and disinfecting	Not applicable
7.7	Practical performance	See Note 1
7.8	Finish of parts	Not applicable
7.9.1	Total inward leakage	± 4.8%
7.9.2	Penetration of filter material - Sodium chloride	± 4.8%
7.9.2	Penetration of filter material - Paraffin oil	± 4.3%
7.10	Compatibility with skin	Not applicable
7.11	Flammability	See Note 1
7.12	CO ₂ content of the inhalation air	± 8.0%
7.13	Head harness	Not applicable
7.14	Field of vision	See Note 1
7.16	Breathing resistance	± 4.9%
7.17.2	Breathing resistance after clogging	± 7.7%
7.17.3	Filter penetration after clogging - Sodium chloride	± 4.8%
7.17.3	Filter penetration after clogging - Paraffin oil	± 4.3%
7.18	Demountable parts	Not applicable

Note 1 The acceptance criterion for this test is a straightforward "Pass/Fail", rather than a numerical value. Consequently, as there is no value to be reported, uncertainty has not been reported either.

Note 2 The uncertainty value is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which provides for a confidence level of approximately 95%. Values expressed as a percentage (%) are relative.

Note 3 It should be noted that the above values have not been taken into account when making assessment to the pass/fail criteria.

Nameplate

Disposable respirator mask FFP2

Model: 170*95mm

Classification: FFP2 NR

EN149:2001+A1:2009



LOT 2022/03

Made in china

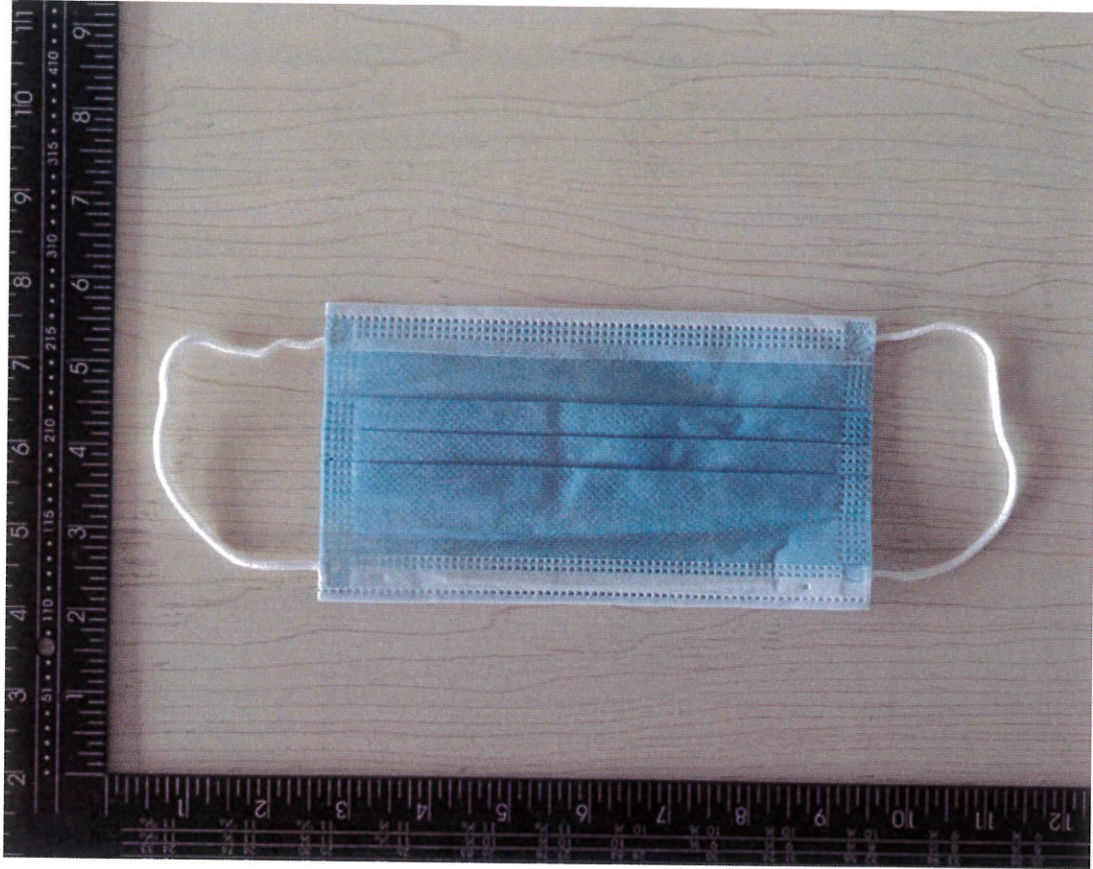
ANNEX

This Annex comprises one
section.

1. Photographs of the products.

END OF FILE

Disposable respirator mask FFP2



170*95mm



Certificate

ICR Polska/CE/V/ 00RE764

**Name and address
of certificate owner:**

**Name and address
of manufacturer:**

Product name: Disposable respirator mask FFP2

Product types: 170*95mm

Product trademark: n/a

- This certificate confirms that the product meets the requirements of the following standard
 - The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Directive** (EU)2016/425 Personal protective equipment
EN 149 : 2001 + A1 : 2009

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.: QA2020032821

Test conducted by: Institute of Textile Technology Testing Center

Certificate issue date: 04.04.2020

Expiration date: 03.04.2025

NOTES:

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued

Certificate modifications: n/a



Director: Rafał Kalinowski

Warsaw, 04.04.2020

