Test Report 3557185 Issue 2.

Basaran Is Elbiseleri ve Is Guvenligi Ekp. San. Tic. Ltd. Sti.

Introduction.

This report has been prepared by S Hickman and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3557185**	Basaran Is Elbiseleri ve Is Guvenligi Ekp. San. Tic. Ltd. Sti.
Job type:	Testing Samples Submitted	Demokrasi Caddesi Seruven Sokak
Start Date:	04/01/2022	No:3 Orhanli
Test type:	Type	Istanbul
Sample ID:	10200445	Tuzla
Registration:	**CE 739634**	34956
Scheme:	Negative Pressure RPE	Turkey
Protocol:	PP123	
Scheme Manager:	Nathan Shipley	

The report has been approved for issue by M Mayo – Testing Team Manager

Approved For Issue	
	Issue Date: 8 February 2023

Objectives.

This is an independent Type Test evaluation to BS EN 149:2001 + A1:2009.

Product Scope.

Respiratory protective device - Filtering half masks to protect against particles.

Report Summary.

The samples were received on 15 November 2021 and the testing was started on 4 January 2022.
Issue 2 of this report supersedes all previous issues. The amendments on all pages giving rise to this issue can be ascertained by contacting the authorising signatory.
Results from BSI report 3662290 are included in this report.

The samples submitted complied with the requirements of the test work conducted.

Test Samples.

Sample ID	ER Number	Description
1 to 46	10200445	Model: ERA 9210 FFP2 V NR D

Description of Test Samples.

Sample Description
Model: ERA 9210 FFP2 V NR D. Valved trifold type filtering half mask with headstrap. White and blue versions of the mask were provided. Testing was split across the two colours. Batch number: PSBR5005112021

Test Requirements.

BS EN 149:2001 + A1:2009
Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7	**Requirements**	-
7.1	**General**	-
7.2	**Nominal values and tolerances**	-
7.3	**Visual Inspection**	Pass - See Note 1
7.4	**Packaging**	N/T - See Note 1
7.5	**Material**	Manufacturer's declaration
7.6	**Cleaning and disinfecting**	N/A - See Note 2
7.7	**Practical performance**	Pass
7.8	**Finish of parts**	Pass
7.9	**Leakage**	-
7.9.1	Total inward leakage	Pass
7.9.2	Penetration of filter material	Pass
7.10	**Compatibility with skin**	Pass
7.11	**Flammability**	Pass
7.12	**Carbon dioxide content of inhalation air**	Pass
7.13	**Head harness**	Pass
7.14	**Field of vision**	Pass
7.15	**Exhalation valves**	Pass
7.16	**Breathing resistance**	Pass
7.17	**Clogging**	-
7.17.1	General	Pass
7.17.2	Breathing Resistance	Pass
7.17.3	Penetration of filter material	Pass
7.18	**Demountable parts**	N/A - See Note 3
9	**Marking**	N/T - See Note 1
10	**Information to be supplied by the manufacturer**	N/T - See Note 1
Appendix A - Test Panel Data		
Product Photographs		

Note 1: Packaging, Marking and Information were not tested, as requested by BSI Product Certification.
Note 2: Single use mask.
Note 3: Not a design feature of this product.

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.
N/T: Not Tested
N/A: Not Applicable
AR: As Received
TC: Temperature Conditioned
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength

Conditions of Issue.

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

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UKAS TESTING
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Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

Test Results.

BS EN 149:2001 + A1:2009
Respiratory protective devices - Filtering half masks to protect against particles.

CLAUSE	REQUIREMENTS	ASSESSMENT
7.1	**General**	
	In all tests all samples shall meet the requirements.	-
7.2	**Nominal values and tolerances**	
	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values, which are not stated as maxima or minima, shall be subject to a tolerance of ±5%. Unless otherwise specified, the ambient temperature for testing shall be (16 – 32) °C, and the temperature limits shall be subject to an accuracy of ± 1°C.	-
7.3	**Visual Inspection**	
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass See Note 1
7.5	**Material**	
	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Pass
	After undergoing the conditioning described in clause 8.3.1 of the standard none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	
	Three particle filtering half masks shall be tested.	Pass
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Manufacturer's declaration
	Testing shall be done in accordance with 8.2.	
7.7	**Practical performance**	
	The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	
	Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.	Pass See Table A
	Testing shall be done in accordance with 8.4.	

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
EH1	1 AR	OK	OK	OK	N/A	Pass
RW1	2 AR	OK	OK	OK	N/A	Pass

7.8	**Finish of parts**	
	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass
	Testing shall be done in accordance with 8.2.	

Note 1: Marking and Information were not tested, as requested by BSI Product Certification.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9	**Leakage**	
7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25% for FFP1 11% for FFP2 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22% for FFP1 8% for FFP2 2% for FFP3 Testing shall be done in accordance with 8.5.	Pass See Table B

Table B: Clause 7.9.1 - Total inward leakage.

Test candidate	Sample/ Pre-test condition	Colour	Inward leakage (%).					
			A	B	C	D	E	Average
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	
PM1	1 AR	Blue	1.8271	1.9263	2.0317	1.9617	2.0667	1.9627
JB1	2 AR	White	0.3633	0.3111	0.2587	0.4388	0.2863	0.3316
BD1	3 AR	Blue	0.3457	0.4022	0.3269	0.3390	0.3250	0.3478
SI1	4 AR	White	2.1235	2.2807	2.3189	1.6935	2.2609	2.1355
JA1	5 AR	White	0.5265	0.5640	0.5299	0.4923	0.6086	0.5575
RF1	6 TC	Blue	0.3283	0.3705	0.3499	0.3420	0.3208	0.3297
JS2	7 TC	White	0.2879	0.3295	0.3372	0.3538	0.3499	0.3317
RW1	8 TC	White	0.2965	0.2375	0.2604	0.3432	0.2641	0.2800
RH1	9 TC	Blue	0.9053	0.9649	1.1255	0.8973	1.0627	0.9911
RS1	10 TC	White	0.2497	0.2943	0.2928	0.2850	0.2619	0.2767

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.9.2	Penetration of filter material	
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1	
	A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on:	Pass See Tables C and D
	3 samples as received,	
	3 samples after the simulated wearing treatment described in 8.3.1.	
	Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed:	Pass See Table E and F
	for non-re-usable devices on:	
	3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2.	
	for re-usable devices on:	
	3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2 and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction.	N/A See Note 1

Table C: Clause 8.11 - Sodium Chloride penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
13	AR	95	6.0	0.5791
14	AR	95	6.0	0.4831
15	AR	95	6.0	0.5541
16	SW	95	6.0	0.6928
17	SW	95	6.0	0.9834
18	SW	95	6.0	2.4193

Table D: Clause 8.11 - Paraffin oil penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
19	AR	95	6.0	3.3440
20	AR	95	6.0	3.9635
21	AR	95	6.0	2.6785
22	SW	95	6.0	3.1215
23	SW	95	6.0	2.6545
24	SW	95	6.0	3.1715

Note 1: Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.9.2 Penetration of filter material (continued)

Table E: Clause 8.11. Exposure test Sodium Chloride.

	Sample 28 MS TC	Sample 29 MS TC	Sample 30 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6.0 %)		
5	2.791577 (See Note 1)	0.355017 (See Note 1)	0.772087 (See Note 1)
10	2.739868	0.314669	0.732997
15	2.621025	0.255175	0.678719
20	2.571425	0.222809	0.622129
25	2.521944	0.192086	0.570550
30	2.510154	0.163301	0.512748
Result	Pass	Pass	Pass

Note 1: The reading at which 5 subsequent sampling intervals showed a declining filter penetration. The testing was terminated without the 120mg exposure limit being reached, as permitted by BS EN 13274-7.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.9.2 Penetration of filter material (continued)

Table F: Clause 8.11 Paraffin oil exposure test.

	Sample 25 MS TC	Sample 26 MS TC	Sample 27 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6.0 %)		
3	2.6825	3.1765	2.9375
5	2.7560	3.2280	2.9745
10	2.9370	3.4800	3.1660
15	3.0695	3.5960	3.2780
20	3.2125	3.8570	3.4110
25	3.2930	3.9030	3.6150
30	3.3660	4.0125	3.6200
35	3.4370	4.1660	3.7270
40	3.5985	4.1105	3.7805
45	3.6095	4.2360	3.9220
50	3.7320	4.3025	3.9995
55	3.8915	4.4145	4.0610
60	3.8710	4.4505	4.1435
Note 1	3.8770	4.4070	4.1475
Result	Pass	Pass	Pass

Note 1: A loading of 120 mg was achieved after a period of 63 minutes, 10 seconds had elapsed.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.10	**Compatibility with skin**	
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Pass
	Testing shall be done in accordance with 8.4 and 8.5.	
7.11	**Flammability**	
	The material used shall not present a danger for the wearer and shall not be of a highly flammable nature.	
	When tested, the particle filtering half mask shall not burn or not continue to burn for more than 5 seconds after removal from the flame.	Pass See Table G
	The particle filtering half mask does not have to be usable after the test.	
	Testing shall be done in accordance with 8.6.	

Table G: Clause 8.6 – Flammability.

Sample	Area exposed	Comments
34 AR	Strap, Side weld, Staple, Nose band	Nil Burn
35 AR	Valve, Filter material, Bottom horizontal weld	Nil Burn
36 TC	Strap, Side weld, Staple, Nose band	Nil Burn
37 TC	Valve, Filter material, Bottom horizontal weld	Nil Burn

7.12	**Carbon dioxide content of inhalation air**	
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).	Pass See Table H
	Testing shall be done in accordance with 8.7.	

Table H: Clause 8.7 - Carbon Dioxide content of the inhalation air.

Sample	Pre-test condition	Limit (%)	Measured (%)
38	AR	1.0	0.54
39	AR	1.0	0.49
40	AR	1.0	0.54

7.13	**Head harness**	
	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	
	The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Pass
	Testing shall be done in accordance with 8.4 and 8.5.	
7.14	**Field of vision**	
	The field of vision is acceptable if determined so in practical performance tests.	Pass
	Testing shall be done in accordance with 8.4.	

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.15	**Exhalation valves**	
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Pass
	Testing shall be done in accordance with 8.2 and 8.9.1.	
	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Pass
	Testing shall be done in accordance with 8.2.	
	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 seconds.	Pass
	Testing shall be done in accordance with 8.3.4.	
	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 seconds.	Pass See Table I
	Testing shall be done in accordance with 8.8.	

Table I: strength of exhalation valve housing.

Sample	Pre-test condition	Requirement (s)	Comments
44	AR	10.0	No visible damage
45	MS	10.0	No visible damage
46	TC	10.0	No visible damage

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.16	**Breathing resistance**	
	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	
	Testing shall be done in accordance with 8.9.	
	A total of 9 valveless particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1.	N/A See Note 1
	Testing shall be done in accordance with 8.9.	
	A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1, and 3 after the flow conditioning in accordance with 8.3.4.	Pass See Tables J, K and L
	Testing shall be done in accordance with 8.9.	

Table J: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
13	AR	30	0.7	0.42
14	AR	30	0.7	0.46
15	AR	30	0.7	0.47
16	SW	30	0.7	0.36
17	SW	30	0.7	0.42
18	SW	30	0.7	0.43
31	TC	30	0.7	0.53
32	TC	30	0.7	0.54
33	TC	30	0.7	0.52
41	AR FT	30	0.7	0.39
42	TC FT	30	0.7	0.40
43	TC FT	30	0.7	0.39

Note 1: Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.16 Breathing resistance (continued)

Table K: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
13	AR	95	2.4	1.56
14	AR	95	2.4	1.86
15	AR	95	2.4	1.70
16	SW	95	2.4	1.37
17	SW	95	2.4	1.51
18	SW	95	2.4	1.53
31	TC	95	2.4	1.75
32	TC	95	2.4	1.83
33	TC	95	2.4	1.79
41	AR FT	95	2.4	1.46
42	TC FT	95	2.4	1.43
43	TC FT	95	2.4	1.47

Table L: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the highest value recorded.

Sample	Pre-test condition	Flow (l/min)	Limit (mbar)	Measured (mbar)
13	AR	160	3.0	1.24
14	AR	160	3.0	1.26
15	AR	160	3.0	1.16
16	SW	160	3.0	1.07
17	SW	160	3.0	1.10
18	SW	160	3.0	1.10
31	TC	160	3.0	1.38
32	TC	160	3.0	1.35
33	TC	160	3.0	1.29
41	AR FT	160	3.0	1.17
42	TC FT	160	3.0	1.19
43	TC FT	160	3.0	1.18

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.17	**Clogging**	
7.17.1	General	
	For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory. Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in clause 8.10 of the standard. The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m^3 is reached.	Pass
7.17.2	Breathing Resistance	
7.17.2.1	Valved particle filtering half masks	
	After clogging the inhalation resistances shall not exceed - FFP1: 4 mbar - FFP2: 5 mbar - FFP3: 7 mbar at 95 l/min continuous flow; The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow. Test in accordance with clause 8.9 of the standard.	Pass See Tables M and N
7.17.2.2	Valveless particle filtering half masks	
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar 95 l/min continuous flow. Test in accordance with clause 8.9 of the standard.	N/A See Note 1

Table M: Clause 8.9 – Breathing resistance. Post clogging inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
47	AR	95	5.0	2.38
48	TC	95	5.0	2.58
49	TC	95	5.0	2.30

Table N: Clause 8.9 – Breathing resistance. Post clogging exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
47	AR	160	3.0	1.40
48	TC	160	3.0	1.32
49	TC	160	3.0	1.39

Note 1: Not a design feature of this product.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
7.17.3	Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in clause 7.9.2 of the standard, for the penetration test according to EN 13274-7, after the clogging treatment. Test in accordance with clause 8.11 of the standard using EN 13274-7	Pass See Tables O and P

Table O: Post clogging Sodium Chloride penetration

Sample	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
47	AR	95	6.0	1.2619
48	TC	95	6.0	2.1010
49	TC	95	6.0	1.5993

Table P: Post clogging Paraffin oil penetration

Sample	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
47	AR	95	6.0	2.7870
48	TC	95	6.0	4.0670
49	TC	95	6.0	3.3310

Appendix A. – Test Panel Data

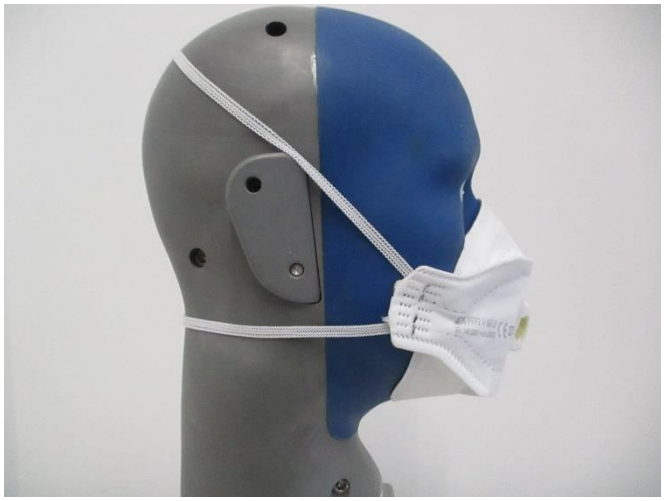
Test Candidate	Facial Dimensions (mm)					Gender
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
PM1	122	154	130	54	615	Male
JB1	114	144	108	59	574	Male
BD1	133	151	117	53	570	Male
SI1	121	135	142	48	575	Male
JA1	117	134	129	49	565	Male
RF1	104	122	121	55	549	Male
JS2	126	142	125	57	575	Male
RW1	110	145	125	60	585	Male
RH1	116	136	114	54	554	Male
RS1	109	141	120	50	545	Female
EH1	115	131	111	49	577	Male

Note: All candidates were clean shaven.

Product photographs.

White model

Front view



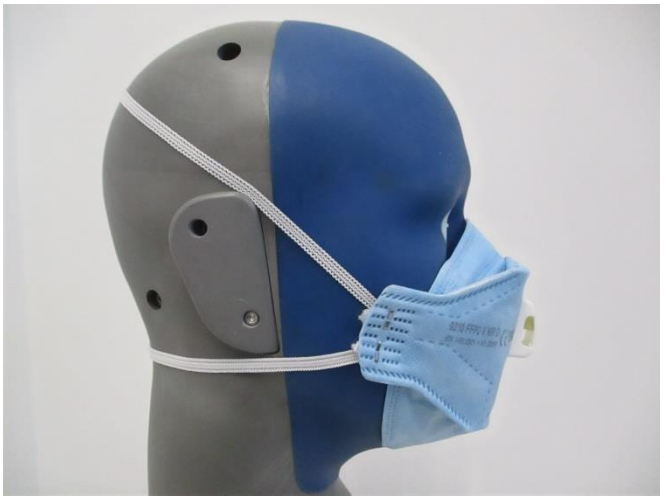
Side view

Inside view

Product photographs. (Continued)

Blue model

Front view



Side view

Inside view

*** End of Report ***