Test Report 3060371 Issue 2.

Profit Royal Pharmaceutical Limited

Introduction.

This report has been prepared by James Bacchus and relates to the activity detailed below:

Job/Registration Details		Client Details
Job number:	**3060371**	Profit Royal Pharmaceutical
Job type:	Testing samples submitted	Rm 1211
Start Date:	13 August 2019	12/F, Sunbeam Centre
Test type:	Type	27 Shing Yip Street
Sample ID:	10185066 & 10186273	Kwun Tong
Registration:	**CE**	Kowloon
Scheme:	PPE CE Pt 10	Hong Kong
Protocol:	PP123	
Scheme Mgr:	Kinga Demetriou	

The report has been approved for issue by Tim Wicksey – Senior Test Engineer

Approved For Issue	
	Issue Date: 6 November 2019

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 8 August 2019 and the testing was started on 13 August 2019.

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

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. This includes the change of Model name to M0011.

Test Samples.

Sample Id	ER Number	Description
1 - 40	10185066	FFP2 Valveless particle filtering half mask (foil packaging)
41 - 62	10186273	FFP2 Valveless particle filtering half mask. (clear plastic packaging)

Description of Test Samples.

Sample Description
NASK M0011 particle filtering half mask.

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
7.4	**Packaging**	N/T (1)
7.5	**Material**	Pass
7.6	**Cleaning and disinfecting**	N/A (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**	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**	N/A (3)
7.17.1	General	N/A (3)
7.17.2	Breathing Resistance	N/A (3)
7.17.2.1	Valved particle filtering half masks	N/A (3)
7.17.2.2	Valveless particle filtering half masks	N/A (3)
7.17.3	Penetration of filter material	N/A (3)
7.18	**Demountable parts**	N/A (3)
9	**Marking**	N/T (1)
10	**Information to be supplied by the manufacturer**	N/T (1)
Appendix A - Test Panel Data		
Product Photographs		

(1) Packaging, Marking and Information not assessed as requested by BSI Product Certification
(2) Single use mask
(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
MMDF: Manufactures Minimum Design Flow

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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BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

UKAS TESTING
0135

Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
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 (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 detailed 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.	Pass
	Testing shall be done in accordance with 8.2.	

(1) Marking and user information were not assessed as requested by BSI Product Certification

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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
BH2	1 AR	None
SI1	2 AR	None

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.	

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	Inward leakage (%).					
			A	B	C	D	E	Average
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	
SI1	3	AR	0.2042	1.3480	0.5320	0.3938	0.2691	0.5494
SM1	4	AR	0.2994	0.4037	0.3352	0.3658	0.3090	0.3426
NM1	5	AR	0.5121	0.5054	0.5332	0.7008	0.4378	0.5380
SF2	6	AR	0.3172	0.4220	0.4004	0.5185	0.4098	0.4136
MM2	7	AR	0.3429	0.3638	0.4336	0.4822	0.4234	0.4092
GR1	8	TC	0.4388	0.4521	0.5051	0.6934	0.5720	0.5323
RF1	9	TC	0.5114	0.8786	0.4507	0.7446	0.8213	0.6813
JB1	10	TC	1.0001	1.0565	0.9758	1.1062	1.0809	1.0439
OR1	11	TC	0.4142	0.3991	0.5149	0.6401	0.5646	0.5066
LF1	12	TC	1.0353	2.8122	2.6993	2.5894	2.3906	2.3054

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, 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, 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 instructions.	N/A (1)

Table C: Clause 8.11 - Sodium Chloride penetration test.

Sample	Pre-test condition	Continuous flow (l/min)	Penetration (%)	
			Limit	Measured
41	AR	95	6.0	0.0579
42	AR	95	6.0	0.0373
43	AR	95	6.0	0.1211
44	SW	95	6.0	0.1744
45	SW	95	6.0	0.1118
46	SW	95	6.0	0.1209

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	0.1835
20	AR	95	6.0	0.3195
21	AR	95	6.0	0.3420
22	SW	95	6.0	0.3820
23	SW	95	6.0	0.4965
24	SW	95	6.0	0.4070

(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 53 MS TC	Sample 54 MS TC	Sample 55 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6%)		
5	0.156313	0.083947	0.054683
10	0.142639	0.074547	0.052240
15	0.131128	0.064559	0.048482
20	0.125426	0.056551	0.044692
25	0.118347	0.048622	0.042438
30	0.110191 (1)	0.041120 (1)	0.038827 (1)
Result	Pass	Pass	Pass

(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: 2008.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.9.2 Penetration of filter material (continued)

Table F: Clause 8.11 Paraffin oil exposure test.

	Sample 56 MS TC	Sample 57 MS TC	Sample 58 MS TC
Flow through filter	95 l/min		
Elapsed time (minutes)	Measured penetration % (Maximum permitted penetration 6%)		
3	0.416	0.957	1.1475
5	0.444	0.9955	1.1590
10	0.5015	0.998	1.3185
15	0.544	1.1455	1.4660
20	0.585	1.336	1.5685
25	0.596	1.3735	1.6680
30	0.6115	1.3935	1.7705
35	0.6455	1.4025	1.8435
40	0.6765	1.4980	1.9320
45	0.7465	1.5410	2.0005
50	0.7595	1.5960	2.1010
55	0.8415	1.6325	2.1710
60	0.8585	1.7030	2.2810
63.10	0.916	1.7225	2.3755
Result	Pass	Pass	Pass

(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
59 AR	Filter material, head strap, fastener clip and edge	None
60 AR	Nose band and front weld	None
61 TC	Filter material, head strap, fastener clip and edge	None
62 TC	Nose band and front weld	None

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	0.44
39	AR	1.0	0.39
40	AR	1.0	0.49

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.	N/A (1)
	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.	N/A (1)
	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.	N/A (1)
	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.	N/A (1)
	Testing shall be done in accordance with 8.8.	

(1) Not a feature of this product

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.	Pass See tables I,J, K
	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.	N/A (1)
	Testing shall be done in accordance with 8.9.	

Table I: 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	1.00	0.47
14	AR	30	1.00	0.41
15	AR	30	1.00	0.44
16	SW	30	1.00	0.40
17	SW	30	1.00	0.32
18	SW	30	1.00	0.35
31	TC	30	1.00	0.39
32	TC	30	1.00	0.34
33	TC	30	1.00	0.36

(1) Not a design feature of this product

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT

7.16 Breathing resistance (continued)

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	95	3.0	1.62
14	AR	95	3.0	1.29
15	AR	95	3.0	1.50
16	SW	95	3.0	1.37
17	SW	95	3.0	1.14
18	SW	95	3.0	1.17
31	TC	95	3.0	1.32
32	TC	95	3.0	1.29
33	TC	95	3.0	1.17

Table K: 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	2.22
14	AR	160	3.0	1.88
15	AR	160	3.0	2.08
16	SW	160	3.0	1.95
17	SW	160	3.0	1.68
18	SW	160	3.0	1.83
31	TC	160	3.0	1.81
32	TC	160	3.0	1.71
33	TC	160	3.0	1.66

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 8.10.	
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m^3 is reached.	N/A (1)
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.	N/A (1)
	Testing shall be done in accordance with 8.9.	
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.	N/A (1)
	Testing shall be done in accordance with 8.9.	
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. Testing shall be done in accordance with 8.11 using EN 13274-7:2008	N/A (1)

(1) Not a design feature of this product

Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Gender
	Length of face	Width of face	Face depth	Width of mouth	Head Circumference	
SI1	121	135	142	48	575	M
SM1	107	134	120	55	545	F
NM1	118	142	106	61	570	M
SF2	124	133	123	52	561	F
MM2	119	150	110	53	595	M
GR1	124	145	135	49	590	M
RF1	104	122	121	55	549	M
JB1	114	144	108	59	574	M
OR1	112	123	114	48	554	F
LF1	117	130	130	53	565	M

Note: All candidates were clean shaven

NASK M0011 (Front View)

NASK M0011 (Side view)

NASK M0011 (Fastener clips)

NASK M0011 (Interior view)

END OF REPORT