



VERIDIA

Certification Pack.

N95 BYD Face Mask.

73700



This pack contains
TGA Certificate
EN Test Report
ASTM 2100 Test Report

Date Released

November 2020

Certification Pack 73700 | Veridia Australia



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 337767 BYD AUSTRALIA PTY LTD - Surgical/medical respirator, single-use

ARTG entry for Medical Device Included Class 1
Sponsor BYD AUSTRALIA PTY LTD
Postal Address Unit 11 9-11 Chaplin Drive, Lane Cove West, NSW, 2066
Australia
ARTG Start Date 12/06/2020
Product Category Medical Device Class 1
Status Active
Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
BYD Precision Manufacture Co Ltd	No 1 Baoping Road Long gang District, Shenzhen, China

Products**1 . Surgical/medical respirator, single-use**

Product Type	Single Device Product	Effective Date	12/06/2020
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	The N95 Healthcare particulate respirator is designed to cover the nose and mouth of a healthcare worker to permit normal breathing while protecting the wearer and patient from particles during medical, surgical, dental, and isolation procedures. It is a single-use device.		

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary



中国认可
国际互认
检测
TESTING
CNAS L1499

National Quality Supervision and Testing Center for Personal
Protective Equipment (Beijing)
(Testing Laboratory for Labour Protection Products of Beijing
Municipal Institute for Labour Protection)

No.55 Taoranting Street, Xicheng District, Beijing, China.
Phone: +86 10 63519250 +86 10 63520770 +86 10 83530311
Fax: +86 10 63519250 +86 10 63520770

The Testing Center is accredited for compliance with ISO/IEC 17025.

The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.

CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles —
Requirements, testing, marking

Product: Particle filtering half mask

Report No: 2020 (D) - 0615

Client: CCQS Certification Services Limited

Model (s): DE2323

Date(s) of tests: 2020.05.03-2020.05.16

DESCRIPTION OF SAMPLES

General Information	Classification	Main Components
	FFP2 NR	White folding mask
Manufacturer	BYD Precision Manufacture Co., Ltd.	
Manufacturer Address	No.3001 Baohe Road, Baolong Industrial City, Longgang Street, Longgang District, Shenzhen, P. R China	

Signed:

Issued: 2020.5.16

陈倬为 Chen Zhuowei

Authorized Signatory, Lab Director

Page 1 of 10



This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

国家劳动防护用品质量监督检验中心(北京)

Conditions:

The test results presented in this report relate to the samples tested only.

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

The authenticity of this test report and its contents can be verified by contacting the laboratory.

Test Results

7.3 Visual inspection

Not tested¹

The visual inspection shall include the marking and information supplied by the manufacturer.

Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package

Pass²

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

Note2: In accordance with the requirement.

7.5 Material

Pass³

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.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting

N/A⁴

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

Note4: Single shift use only.

7.7 Practical performance

Pass⁵

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note5: No imperfections.

7.8 Finish of parts

Pass⁶

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage

Pass⁷

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

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material

Pass⁸

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%

This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

Report No: 2020 (D) - 0615

Page 4 of 10

FFP2 $\leq 6\%$ $\leq 6\%$ FFP3 $\leq 1\%$ $\leq 1\%$ **Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.****7.10 Compatibility with skin****Pass⁹**

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.

Note9: No irritation or any other adverse effect to health.**7.11 Flammability****Pass¹⁰**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Note10: Test results are shown in Annex A Table 7.11.**7.12 Carbon dioxide content of the inhalation air****Pass¹¹**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)

Note11: Test results are shown in Annex A Table 7.12.**7.13 Head harness****Pass¹²**

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.

Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.**7.14 Field of vision****Pass¹³**

The field of vision is acceptable if determined so in practical performance tests.

Note13: Pass the practical performance tests.**7.15 Exhalation valve****N/A¹⁴**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

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.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note14: No exhalation valve.**7.16 Breathing resistance****Pass¹⁵**

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

7.17 CloggingN/A¹⁶**7.17.2 Breathing resistance**

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note16: Single shift use only.

7.18 Demountable partsN/A¹⁷

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note17: No demountable parts.

9 Marking

Not tested

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

Report No: 2020 (D) - 0615

Page 6 of 10

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

Annex A: Summarization of Test Data**Table 7.9.1-A Inward leakage test data**

Test specification: EN 149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	9.13	9.29	9.61	9.41	9.22	9.3
Gong	2	A.R.	6.33	6.61	6.61	6.61	6.43	6.5
Yu	3	A.R.	7.10	7.15	7.12	7.40	7.36	7.2
Hu	4	A.R.	7.32	7.47	7.64	7.71	7.51	7.5
Xu	5	A.R.	7.89	8.48	7.91	7.91	8.33	8.1
Deng	6	T.C.	6.32	6.75	6.78	6.45	6.46	6.6
Zhang	7	T.C.	6.62	6.70	6.70	7.05	6.86	6.8
Liu	8	T.C.	6.11	6.58	6.13	6.14	6.13	6.2
Fang	9	T.C.	7.11	7.12	7.43	7.43	7.22	7.3
Lv	10	T.C.	7.20	7.72	7.61	7.60	7.50	7.5
All <u>50</u> individual exercise results were not greater than <u>11</u> % <u>8</u> out of <u>10</u> individual wearer arithmetic means were not greater than \leq <u>8</u> %							Pass	

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.245	Pass
		12	0.226	
		13	0.385	
	Simulated wearing treatment	14	0.431	
		15	0.444	
		16	0.517	
	Mechanical strength+ Temperature conditioned	17	0.498	
		18	0.572	
		19	0.616	
Paraffin oil test	As received	20	2.24	
		21	2.15	
		22	2.16	
	Simulated wearing treatment	23	2.51	
		24	2.54	
		25	2.47	
	Mechanical strength+ Temperature conditioned	26	2.81	
		27	2.84	
		28	2.73	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 1 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 2 s	
	32	Burn for 1 s	

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result		Assessment
As received	33	0.41%	Mean value 0.4%	Pass
	34	0.42%		
	35	0.41%		

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149-2001 Clause 8.9

Test Specification EN 149:2001 Grade 05																	
As received	Flow rate		36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.5	0.5	0.6	0.6	0.5	0.5	0.5	0.5	0.5	0.4	0.4	0.6	0.5	0.6
		95 l/min	1.5	1.6	1.5	1.7	1.7	1.7	1.6	1.7	1.6	1.6	1.6	1.6	1.6	1.5	1.5
Exhalation	160 l/min	1.6	1.7	1.8	1.7	1.8	1.7	1.7	1.8	1.7	1.8	1.6	1.6	1.7	1.8	1.6	
Simulated wearing treatment	Flow rate		39					40					41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.6	0.5	0.6	0.6	0.5	0.5	0.4	0.4	0.5	0.6	0.4	0.5	0.6	0.4	0.6
		95 l/min	1.6	1.6	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.5	1.5	1.7	1.6	1.6	1.7
Exhalation	160 l/min	1.7	1.8	1.8	1.7	1.8	1.6	1.7	1.8	1.8	1.7	1.8	1.7	1.7	1.7	1.7	
Temperature conditioned	Flow rate		42					43					44				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.5	0.6	0.4	0.6	0.5	0.5	0.5	0.6	0.5	0.4	0.5	0.6	0.4	0.4	0.4
		95 l/min	1.7	1.6	1.7	1.6	1.6	1.5	1.7	1.5	1.7	1.7	1.6	1.6	1.7	1.6	1.7
Exhalation	160 l/min	1.8	1.7	1.6	1.7	1.7	1.6	1.7	1.6	1.7	1.7	1.7	1.8	1.7	1.7	1.8	
Assessment	Pass																

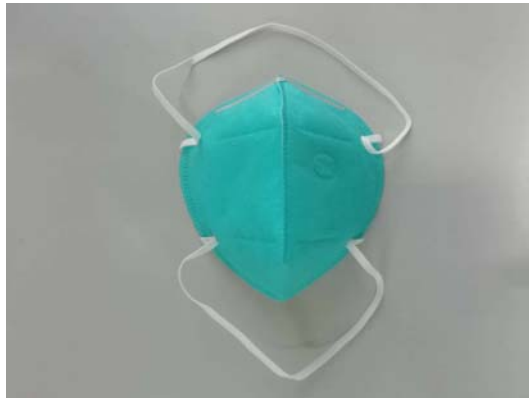
A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

End of Annex A

Report No: 2020 (D) - 0615

Page 10 of 10

ANNEX B PHOTOS OF SAMPLES



End of Annex B

This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

国家劳动保护用品质量监督检验中心(北京)

TEST REPORT

Prepared For :	BYD Precision Manufacture Co., Ltd. No.3001 Baohe Road, Baolong Industrial City, Longgang Street, Longgang District, Shenzhen, Guangdong Province, China
Trade Mark :	N/A
Product Name :	BYD N95 Particulate Respirator Mask
Model(s) :	N/A
Number:	One hundred
Prepared By:	Shenzhen CCT Testing Technology Co., Ltd. 8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China Tel: +86 755-3315 7675 Fax: +86 755-33609691 Email: cct@cct-prc.com Web: www.cct-prc.com
Test Date:	Mar. 24, 2020 - Apr. 2, 2020
Date of Report:	Apr. 2, 2020
Report No. :	CCT20032405TRS

Note: This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Shenzhen CCT Testing Technology Co., Ltd.

TEST REPORT ASTM F-2100 Standard Specification for Performance of Materials Used in Medical Face Masks 1	
Reference No.....	CCT20032405TRS
Date of issue.....	Apr. 2, 2020
Contents	6 pages
Testing laboratory	
Name	Shenzhen CCT Testing Technology Co., Ltd.
Address	8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China
Testing location	Same as above
Client	
Name	BYD Precision Manufacture Co., Ltd.
Address	No.3001 Baohe Road, Baolong Industrial City, Longgang Street, Longgang District, Shenzhen, Guangdong Province, China
Test specification	
Standard	ASTM F-2100
Procedure deviation	N.A.
Non-standard test method	N.A.

**Test case verdicts**

Test case does not apply to the test object : N(.A.)

Test item does meet the requirement..... : P(ass)

Test item does not meet the requirement..... : F(ail)

Testing

Date of receipt of test item: Mar. 24, 2020

Date(s) of performance of test From Mar. 24, 2020 to Apr. 2, 2020

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item tested.

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

Remark :

The product complies with requirements of the standard.



Serial number	Test item	Standard Requirements	Standard	Single item conclusion
1	Hight Fluid Resistance	160mm Hg	ASTM F-2100 Level 3	P
2	Bacterial filtration efficiency (BFE)	The bacterial filtration efficiency of mask shall be $\geq 98\%$		P
3	Particulate filtration efficiency(PFE)	The Particulate filtration efficiency of mask shall be $\geq 98\%$		P
4	Flame spread	Class 1		P
5	Filtration efficiency	The Filtration efficiency $\geq 95\%$	NIOSH 42 CFR PART 84	P
6	Exhalation Resistance Test	$\leq 35\text{mm H}_2\text{O}$		P
7	Inhalation Resistance Test	$\leq 25\text{mm H}_2\text{O}$		P

Test Results

Bacterial Filtration Efficiency			P
Models Item	Sample 1	Sample 2	Sample 3
BFE (%)	99.96	99.98	99.96

Sub-Micron Particulate Filtration			P
Models Item	Sample 1	Sample 2	Sample 3
Sub-Micron Particulate Filtration at 0.1 micron (%)	99.96	99.94	99.94

Filtration efficiency			P
Models Item	Sample 1	Sample 2	Sample 3
Filtration efficiency (%)	99.72	99.76	99.68

Exhalation Resistance Test			P
<div>Models Item</div>	Sample 1	Sample 2	Sample 3
Exhalation Resistance (mmH ₂ O)	16.5	16.2	17.0

Inhalation Resistance Test			P
<div>Models Item</div>	Sample 1	Sample 2	Sample 3
Inhalation Resistance (mmH ₂ O)	15.7	15.7	15.7

Attachments: real photos**Photo 1****Photo 2**

***** **END OF THE REPORT** *****