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TEST REPORT

EN 149:2001+A1:2009 欧盟EN149:2001+A12009标准
Filtering half masks to protect against particles

Report no: WLH0664-2020 编号
Product: Particle Filtering Half Mask
Model(s): RSN99V
Main components: Mask body, with exhalation valve
Date(s) of tests: 03th Jun~19th Jun 2020

Client

CCQS Certification Services Limited

欧盟CCQS认证

Block 1 Blanchardstown Corporate Park,
 Ballycoolin Road, Blanchardstown, Dublin15,
 D15 AKK1, Ireland

Client order: /

Order(s) received: Jun, 2020

Manufacturer

**Dongguan Rysam Medical Equipment
 Manufacturing Co., Ltd.**

No. 302, Building, Dongkeng Village, DongGuan City,
 Guangdong Province, China

Contact: /

E-mail: /

Phone: /

Conditions:

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The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the CASST.

Any objection should be submitted within 2 weeks from the date of receipt of the report, and it will not be accepted after the deadline.

Specimens will be disposed of 4 weeks from the date of this report, unless otherwise instructed.

Signed:

张明明/Zhang Mingming, Authorized Signatory

Issued: 2020-06-19

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Product characteristics 检测的产品信息

Property	Characteristic
Model	RSN99V
Classification claimed	FFP3 NR
Exhalation valve(s)	Single

品名: RSN99V

类型: FFP3 NR

呼吸阀: 单个

Submission details

Product	Quantity	Date received	Specimen No.
RSN99V Particle Filtering Half Mask	86 送检数量	03 th Jun 2020 送检日期	WLH0664-2020-01 to -86 样品编号

Photographs of the products tested 检测产品照片

Dongguan Rysam Medical Equipment Manufacturing Co., Ltd.'s Model RSN99V Particle Filtering Half Mask



CASSTspecimennumberWLH0664-2020-03

Procedures 检测程序按照: 欧盟EN 149:2001+A12009标准

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with EN 149:2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received.

7.9.2 Penetration of filter material

气溶胶过滤材料渗透测试 通过 Pass

The penetration of the filter of the particle filtering half mask shall meet the requirements:

Classification 类别	Maximum penetration of test aerosol 测试气溶胶渗透的最大余量			
	Sodium chloride test 95 l/min, %, 氯化钠测试 Max 95升/分钟		Paraffin oil test 95 l/min, %, 石蜡油测试 Max 95升/分钟	
FFP1 达标要求	20%以内	20		20%以内 20
FFP2 达标要求	6%以内	6	过滤率94%	6%以内 6 过滤率94%
FFP3 达标要求	1%以内	1	过滤率99%	1%以内 1 过滤率99%

Sodium chloride test results: (Pass) 氯化钠过滤测试结果 通过

Specimen 口罩样品	Condition 检测方式	Penetration (%)	
		After 3 minutes 检测时间3分钟以后	Max. during exposure
-06	A.R.	0.16 99.84%过滤	
-24		0.25 99.75%过滤	
-45		0.54 99.46%过滤	
-09	S.W.	0.46 99.54%过滤	
-39		0.71 99.29%过滤	
-50		0.12 99.88%过滤	
-29	M.S. + T.C.	0.14 99.86%过滤	0.40 99.6%过滤
-55		0.21 99.79%过滤	0.26 99.84%过滤
-62		0.17 99.83%过滤	0.19 99.81%过滤
Maximum permitted		检测平均最大余量为0.034%	1 检测结果99.6%过滤率

最大余量 要求1%以内

Paraffin oil test results: (Pass) 石蜡油过滤测试结果 通过

Specimen 口罩样品	Condition 检测方式	Penetration (%)	
		After 3 minutes 检测时间3分钟以后	Max. during exposure
-12	A.R.	0.28 99.72%过滤	
-38		0.19 99.81%过滤	
-52		0.32 99.68%过滤	
-18	S.W.	0.40 99.60%过滤	
-47		0.35 99.65%过滤	
-72		0.45 99.55%过滤	
-30	M.S. + T.C.	0.70 99.30%过滤	0.72 99.28%过滤
-54		0.44 99.56%过滤	0.52 99.42%过滤
-76		0.43 99.57%过滤	0.50 99.50%过滤
Maximum permitted		检测平均最大余量为0.044%	1 检测结果99.5%过滤率

最大余量 要求1%以内

7.10 Compatibility with skin与皮肤的兼容性测试 通过 Pass⁶

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.

Note 6: Specimens -03, -15, -27, -39, -57 (A.R.) and specimens -07, -20, -31, -48, -60 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability

可燃性测试 通过 Pass

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.

燃烧时从火焰上取下后持续燃烧超过5秒

Specimen	Condition	Results	结果
-10	A.R.	burn for 0.5 s	0.5秒熄灭
-43		burn for 0.8 s	0.8秒熄灭
-19	T.C.	burn for 0.6 s	0.6秒熄灭
-56		burn for 0.6 s	0.6秒熄灭

7.12 Carbon dioxide content of the inhalation air 吸入空气二氧化碳余量测试 通过 Pass

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

测试要求: 吸入空气二氧化碳余量不得超过总吸入量的1%(死腔率)

Specimen	CO ₂ (%)	二氧化碳余量%
-71	0.31	99.69%换气率
-75	0.24	99.76%换气率
-80	0.29	99.71%换气率
Maximum permitted	1.0	

最大余量要求1% 达到99%换气率 测试结果平均值0.028达到99.72%换气率

7.13 Head harnessPass⁷

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

头带, 戴上、取下、调节、稳固、稳定测试 通过

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.

Note 7: Specimens -11, -25, -37, -58, -66 (A.R.) and specimens -16, -32, -44, -61, -73 (T.C.) were tested. Head harness (adjustable head straps) can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 Field of vision视野测试 通过 Pass⁸

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

Note 8: Specimens -05 and -34 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve

呼吸阀测试 通过 Pass⁹

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 face blank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note 9:

There were no observed problems during testing of function in all orientations. See 7.16 for results.

The valve was protected against dirt and mechanical damage by a shroud.

The product satisfied leakage requirements. See 7.9.1 for results.

There were no observed problems when assessing operation after high exhalation flow.

See 7.16 for results.

The valve housing withstood 10N applied for 10s. Specimens -84 (A.R.), -86 (T.C.) and -85(M.S.) were tested.

7.16 Breathing resistance

呼吸阻力测试 通过 Pass¹⁰

Classification 产品分类	Maximum permitted resistance (mbar) 最大呼吸阻力合格率		
	inhalation 吸气		exhalation 呼气
	30 l/min 30升/分钟	95 l/min 95升/分钟	160 l/min or 160升/分钟 (25 cycles/min×2.0 l/stroke)
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0 合格率3.0以内

合格率1.0以内 合格率3.0以内

Note 10: FFP3 Filtering face mask. Test results are detailed below.

FFP3检测结果如下:

Result details 结果明细**7.4 Packaging**

NRq

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.

7.5 Material材料检测 通过 Pass¹

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.

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.

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

Note 1: In accordance with the requirement.

Specimens -04, -35, -53 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.

Specimens -13, -41, -64 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 Cleaning and disinfectingNAP²

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.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Note 2: Single shift use only.

7.7 Practical performance实用性能没有瑕疵 通过 Pass³

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

Note 3: No imperfections.

Specimen and subject details:

Specimen	Subject
-23	ZMM
-46	SM

7.8 Finish of parts产品佩戴的安全性：没有毛边或尖刺 通过 Pass⁴

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

Note 4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.