



中国认可
国际互认
检测
TESTING
CNAS L10118



国检检测
CHINA COMPONENTS TEST

Test Report

(2020) WSZ FHL NO.3118

Product Name PROTECTIVE RESPIRATOR

Client Zhejiang Xinna Medical Devices Technology Co., Ltd

Manufacturer Zhejiang Xinna Medical Devices Technology Co., Ltd

Test Type Entrusted inspection




Jiangsu Guojian Testing Technology Co., Ltd

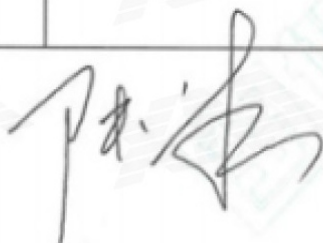
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| | | | |
|----------------------|---|--|--------------|
| Product name | PROTECTIVE RESPIRATOR | Specification | D1 |
| | | Brand | — |
| Client/Add/Tel | ZHEJIANG XINNA MEDICAL DEVICES TECHNOLOGY CO., LTD/Huangnikan Industrial Zone, Yucheng Street, YuHuan City, China/— | | |
| Manufacturer/Add/Tel | ZHEJIANG XINNA MEDICAL DEVICES TECHNOLOGY CO., LTD/Huangnikan Industrial Zone, Yucheng Street, YuHuan City, China/— | | |
| Sample grade | FFP2 | Sample number | GW0020-2020 |
| Sample quantity | 110 pcs | Receiving date of sample | 23/03/2020 |
| Test type | Entrusted inspection | Article number/Batch number/Style number | — |
| Test date | 01/04/2020~14/04/2020 | Testing sites | Testing room |
| State | Meeting the the requirements of testing | | |
| Test standard(s) | BS EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles- Requirements,testing, marking | | |
| Test items | Visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage | | |
| Test conclusion | <p>The sample upon testing, the test items meet the requirements of the BS EN 149:2001+A1:2009 standard. The detail of test results see on Pages 2-5.</p> <p>Issue date: 2020.4.17</p> | | |
| Note | <p>For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.</p>  | | |

Approver:



Reviewer:

万恒

Chief Tester:

杨美

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| S.No. | Test item | | Unit | Technical requirements | Test result | | Single item decision |
|-------|-------------------------|------------------------|------|--|--|---|----------------------|
| 1 | Visual inspection | Packaging | — | 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. | Packaging withstand mechanical damage and contamination. | | Qualified |
| | | 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. | Materials withstand handling and wear. | | |
| 2 | Practical performance | Head harness comfort | — | Head harness should be comfort. | Sample 1 has the feeling of comfortable wearing | | Qualified |
| | | | | | Sample 2 has the feeling of comfortable wearing | | |
| | | Security of fastenings | — | Fastenings are safe and reliable | Sample 1: All fastenings are firm. | | |
| | | | | | Sample 2: All fastenings are firm | | |
| | | Field of vision | — | Field of vision is acceptable | Samples 1: Having a wider visual field | | |
| | | | | | Samples 2: Having a wider visual field | | |
| 3 | Finish of parts | | — | Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. | Parts of the device have no sharp edges and burrs | | Qualified |
| 4 | 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. | A.R. | 5 pcs all don't cause irritation | Qualified |
| | | | | | T.C. | 5 pcs all don't cause irritation | |
| 5 | Flammability | | — | When tested,the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame. | A.R. | The Sample is burning. Burning time:0.1s | Qualified |
| | | | | | | The Sample is burning. Burning time:0.1s | |
| | | | | | T.C. | The Sample is burning. Burning time:0.1s | |
| | | | | | | The Sample is burning. Burning time:0.1s | |

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| S.No. | Test item | | Unit | Technical requirements | Test result | | | | Single item decision |
|-------|--|-----------------|------|---|---|--|------|------|----------------------|
| 6 | Carbon dioxide content of the inhalation air | | | ≤1.0% (by volume) | 0.09% | | | | Qualified |
| 7 | Material | | — | After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. | Sample 1: either facepiece nor straps have mechanical failure | | | | Qualified |
| | | | | | Sample 2: either facepiece nor straps have mechanical failure | | | | |
| | | | | | Sample 3: either facepiece nor straps have mechanical failure | | | | |
| | | | | After undergoing S.W. and T.C. , none of the particle filtering half masks shall not collapse. | Sample 1: no collapse | | | | |
| | | | | | Sample 2 : no collapse | | | | |
| | | | | | Sample 3: no collapse | | | | |
| 8 | 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 | A.R. | All of 5 pieces particle filtering half mask meet the requirements | | | Qualified |
| | | | | | T.C. | All of 5 pieces particle filtering half mask meet the requirements | | | |
| 9 | Field of vision | | — | The field of vision is acceptable if determined so in practical performance tests. | The two samples both have a wider visual field | | | | Qualified |
| 10 | Penetration of filter material | sodium chloride | — | ≤6% | A.R. | 0.4% | 0.5% | 0.4% | Qualified |
| | | | | | S.W. | 0.2% | 0.4% | 0.3% | |
| | | | | | M.S+T.C. | 0.9% | 0.8% | 0.9% | |
| | | Paraffin oil | — | ≤6% | A.R. | 2.2% | 2.4% | 2.1% | Qualified |
| | | | | | S.W. | 2.0% | 2.1% | 2.4% | |
| | | | | | M.S+T.C. | 2.9% | 3.0% | 3.1% | |

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|-------------|----------------------|---------------------|------|------------------------|-------------|-----------------------|---------------------------|-----------------------------|------------------------|-------------------------|----------------------|
| S.No | Test item | | Unit | Technical requirements | Test result | | | | | | Single item decision |
| | | | | | Exercises | Facing directly ahead | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side | |
| 11 | Breathing resistance | Inhalation 30 L/min | mbar | ≤0.7 | A.R. | 0.3 | 0.3 | 0.2 | 0.2 | 0.2 | Qualified |
| | | | | | | 0.2 | 0.3 | 0.2 | 0.3 | 0.3 | |
| | | | | | | 0.2 | 0.2 | 0.2 | 0.2 | 0.3 | |
| | | | | | S.W. | 0.2 | 0.3 | 0.2 | 0.3 | 0.2 | |
| | | | | | | 0.2 | 0.3 | 0.3 | 0.3 | 0.2 | |
| | | | | | | 0.3 | 0.2 | 0.3 | 0.2 | 0.3 | |
| | | | | | T.C. | 0.2 | 0.3 | 0.2 | 0.2 | 0.3 | |
| | | | | | | 0.3 | 0.3 | 0.2 | 0.2 | 0.3 | |
| | | | | | | 0.3 | 0.2 | 0.3 | 0.3 | 0.2 | |
| | | Inhalation 95 L/min | mbar | ≤2.4 | A.R. | 0.6 | 0.7 | 0.7 | 0.6 | 0.7 | Qualified |
| | | | | | | 0.7 | 0.6 | 0.7 | 0.6 | 0.7 | |
| | | | | | | 0.7 | 0.7 | 0.7 | 0.6 | 0.7 | |
| | | | | | S.W. | 0.6 | 0.6 | 0.7 | 0.6 | 0.7 | |
| | | | | | | 0.6 | 0.7 | 0.7 | 0.7 | 0.6 | |
| | | | | | | 0.7 | 0.6 | 0.7 | 0.6 | 0.6 | |
| | | | | | T.C. | 0.6 | 0.7 | 0.6 | 0.7 | 0.6 | |
| | | | | | | 0.7 | 0.6 | 0.6 | 0.6 | 0.7 | |
| | | | | | | 0.7 | 0.6 | 0.6 | 0.6 | 0.6 | |
| | Exhalation 160 L/min | mbar | ≤3.0 | A.R. | 1.2 | 1.1 | 1.0 | 1.0 | 1.0 | Qualified | |
| | | | | | 1.1 | 1.2 | 1.0 | 1.0 | 1.2 | | |
| | | | | | 1.0 | 1.1 | 1.0 | 1.0 | 1.1 | | |
| | | | | S.W. | 1.1 | 1.1 | 1.0 | 1.0 | 1.0 | | |
| | | | | | 1.0 | 1.0 | 1.0 | 1.2 | 1.1 | | |
| | | | | | 1.0 | 1.2 | 1.0 | 1.0 | 1.0 | | |
| | | | | T.C. | 1.2 | 1.1 | 1.1 | 1.0 | 1.1 | | |
| | | | | | 1.1 | 1.0 | 1.2 | 1.1 | 1.1 | | |
| | | | | | 1.1 | 1.2 | 1.1 | 1.1 | 1.2 | | |

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| S.No. | Test item | Unit | Technical requirements | Test result | | | | | | | Single item decision |
|-------|----------------------|------|--|-------------|--------|--------|--------|--------|--------|---------|----------------------|
| 12 | Total inward leakage | — | At least 46 out of the 50 individual exercise results shall be not greater than 11%; And in addition,at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%. | Exercises | E1 (%) | E2 (%) | E3 (%) | E4 (%) | E5 (%) | TIL (%) | Qualified |
| | | | | A.R. | 3.0 | 2.6 | 3.0 | 3.1 | 2.7 | 2.9 | |
| | | | | | 3.5 | 4.0 | 5.0 | 3.7 | 2.5 | 3.7 | |
| | | | | | 4.1 | 3.7 | 4.4 | 4.6 | 3.8 | 4.1 | |
| | | | | | 3.9 | 4.1 | 4.5 | 4.0 | 2.9 | 3.9 | |
| | | | | | 2.9 | 4.3 | 4.8 | 4.5 | 4.2 | 4.1 | |
| | | | | T.C. | 4.6 | 5.2 | 4.4 | 3.9 | 3.6 | 4.3 | |
| | | | | | 4.3 | 5.3 | 5.5 | 4.5 | 3.9 | 4.7 | |
| | | | | | 2.9 | 4.9 | 4.0 | 4.5 | 4.5 | 4.2 | |
| | | | | | 3.4 | 4.8 | 4.1 | 3.7 | 2.9 | 3.8 | |
| | | | | | 2.5 | 5.1 | 4.2 | 4.8 | 2.5 | 3.8 | |
| Note | | | | | | | | | | | |

The end