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Test Report

EN 149 : 2001 + A1 : 2009

Report no: 1.13.05.01

Client: INSPEC Certification Services
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(on behalf of): Shanghai Zhongzhi Health Articles Co., Ltd

Client order: TA13/0022

Order(s) received: 26 March 2013

Model(s): ZH3161 and ZH3161V

Date(s) of tests: 27 March to 1 May 2013

Signed:

Peter Threlfall, Laboratory Supervisor

Issued: 2 May 2013

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Conditions

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Summary of assessment*

| Clause | Requirement | Assessment (See Key) | |
|--------|---|-------------------------|----------------|
| | | Model: | |
| | | ZH3161 | ZH3161V |
| 7.4 | Packaging | Ltd | |
| 7.5 | Material | Ltd | Ltd |
| 7.6 | Cleaning and disinfecting | | |
| 7.7 | Practical performance | Ltd | Ltd |
| 7.8 | Finish of parts | Ltd | Ltd |
| 7.9.1 | Total inward leakage | | Pass (FFP2) |
| 7.9.2 | Penetration of filter material: Sodium chloride | | Pass |
| 7.9.2 | Penetration of filter material: Paraffin oil | | Pass |
| 7.10 | Compatibility with skin | Ltd | Ltd |
| 7.11 | Flammability | | Pass |
| 7.12 | Carbon dioxide content of the inhalation air | Pass | |
| 7.13 | Head harness | Ltd | Ltd |
| 7.14 | Field of vision | Ltd | Ltd |
| 7.15 | Exhalation valve(s) | | Pass |
| 7.16 | Breathing resistance | Ltd | Pass |
| 7.17 | Clogging | | |
| 7.18 | Demountable parts | | NAp |
| 9 | Marking | Fail | Fail |
| 10 | Information to be supplied by the manufacturer | Fail | Fail |

Key

| | |
|------|---|
| | Shading shows the clauses requested. Any other clauses were not requested. |
| Pass | Requirement satisfied. |
| Ltd | Testing requested was insufficient completely to verify compliance with the clause. Refer to the “Result details” section for more information. |
| Fail | Requirement not satisfied. Refer to the “Result details” section for more information. |
| NAs | Assessment not carried out. |
| NAP | Requirement not applicable. |
| NT | Requested but not tested due to early termination following failure. |

* Assessment relates only to those specimens which were tested and are the subject of this report.

Product characteristics

| Property | Characteristic | |
|------------------------|----------------|-------------|
| Model | ZH3161 | ZH3161V |
| Classification claimed | Unspecified | Unspecified |
| Exhalation valve(s) | None | Single |
| Usage designation | NR | NR |

Submission details

| Product | Quantity | Date received | INSPEC specimen no. (1A0157 +) |
|-----------------------------|----------|---------------|--------------------------------|
| ZH3161 filtering half mask | 30 | 22 March 2013 | 111 to 160 |
| ZH3161V filtering half mask | 65 | | 201 to 260 |

Procedures

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

Testing was performed in accordance with BS 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 by INSPEC.

- 7.7** The client instructed that practical performance testing be carried out on one specimen of each model.
- Practical performance tests were conducted in simulation of the practical use of the apparatus under the conditions prevailing in the gallery area of the laboratory. The exercises undertaken and the equipment used were as specified in the standard.
- 7.9.2** Filter penetration testing by the paraffin oil method was carried out using a modified Phoenix SG-20 aerosol generator and a Phoenix model JM-6000 photometer or a TEC Services' model PH-3 photometer. These give similar performance to the instruments specified.
- For the 120mg exposure test, the peak penetration during exposure is reported and in addition the penetration after three minutes for comparison purposes.
- During the 120mg exposure test, the sodium chloride penetration showed continued decline and the test was terminated as the product was marked NR.
- 7.16** Exhalation resistance was tested at a continuous flow of 160 l/min.

Result details**7.4 Packaging****Model ZH3161**

The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.

NAs

The masks were packaged in clear plastic bags that gave some protection against mechanical damage or contamination before use.

Pass**7.5 Material****Model ZH3161**

Specimens 121, 122 and 151 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

Pass

Specimens 117 to 119 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.

Pass

The effects of filter media release were not assessed. Manufacturer to certify.

NAs**Model ZH3161V**

Specimens 220 to 225 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.

Pass

Specimens 206 to 210, 217 to 219, 226 to 231, 233, 239, 240, 246 and 247 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.

Pass

The effects of filter media release were not assessed. Manufacturer to certify.

NAs**7.7 Practical performance****Model ZH3161****Specimen and subject details:**

| Specimen | Subject |
|----------|---------|
| 148 | AH |
| 149 | - |

Pass**NAs**

No adverse comments were made following testing.

Model ZH3161V**Specimen and subject details:**

| Specimen | Subject |
|----------|---------|
| 248 | ED |
| 249 | - |

Pass**NAs**

No adverse comments were made following testing.

7.8 Finish of parts**Model ZH3161**

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

Ltd**Model ZH3161V**

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

Ltd**7.9.1 Total inward leakage (%)****Model ZH3161V**

| Subject | Specimen | Cond | Walk | Head side/ side | Head up/down | Talk | Walk | Mean | |
|--------------------------|----------|------|-------|-----------------|--------------|------|------|------|------|
| KDS | 201 | AR | 5.78 | 5.91 | 5.16 | 5.36 | 5.28 | 5.50 | |
| WA | 202 | AR | 3.06 | 3.04 | 5.42 | 1.07 | 1.43 | 2.80 | |
| AH | 203 | AR | 3.70 | 4.38 | 5.14 | 2.15 | 2.25 | 3.53 | |
| JDU | 204 | AR | 8.05 | 7.42 | 7.65 | 9.08 | 6.74 | 7.79 | |
| ED | 205 | AR | 3.92 | 1.02 | 2.65 | 0.40 | 0.96 | 1.79 | |
| VE | 206 | TC | 8.20 | 10.47 | 7.12 | 2.09 | 5.02 | 6.58 | |
| BH | 207 | TC | 4.75 | 4.46 | 5.89 | 1.86 | 1.79 | 3.75 | |
| SMT | 208 | TC | 2.11 | 2.55 | 2.09 | 2.32 | 2.36 | 2.29 | |
| SR | 209 | TC | 10.43 | 3.84 | 2.15 | 2.17 | 2.69 | 4.26 | |
| INH | 210 | TC | 1.11 | 3.01 | 1.38 | 2.85 | 1.53 | 1.98 | |
| Maximum permitted (FFP1) | | | 25 | | | | | 22 | Pass |
| Maximum permitted (FFP2) | | | 11 | | | | | 8 | Pass |
| Maximum permitted (FFP3) | | | 5 | | | | | 2 | Fail |

All 50 individual exercise results were not greater than 25% (FFP1).

Pass

All 10 individual wearer arithmetic means were not greater than 22% (FFP1).

Pass

All 50 individual exercise results were not greater than 11% (FFP2).

Pass

All 10 individual wearer arithmetic means were not greater than 8% (FFP2).

Pass

32 out of 50 individual exercise results were not greater than 5% (FFP3).

Fail

2 out of 10 individual wearer arithmetic means were not greater than 2% (FFP3).

Fail

Subject facial dimensions:

| Subject | Face Length (mm) | Face Width (mm) | Face Depth (mm) | Mouth Width (mm) |
|---------|------------------|-----------------|-----------------|------------------|
| KDS | 102 | 128 | 98 | 49 |
| WA | 121 | 138 | 120 | 56 |
| AH | 119 | 113 | 115 | 50 |
| JDU | 123 | 156 | 132 | 49 |
| ED | 114 | 138 | 100 | 47 |
| VE | 116 | 132 | 115 | 45 |
| BH | 120 | 139 | 108 | 54 |
| SMT | 117 | 131 | 115 | 40 |
| SR | 126 | 137 | 138 | 52 |
| INH | 125 | 153 | 95 | 58 |

7.9.2 Penetration of filter material**Model ZH3161V****Sodium chloride**

| Specimen | Condition | Penetration (%) | | |
|--------------------------|-------------|-----------------|----------------------|------|
| | | After 3 minutes | Max. during exposure | |
| 211 | A.R. | 0.02 | | |
| 212 | | 0.02 | | |
| 213 | | 0.02 | | |
| 220 | S.W. | 0.15 | | |
| 221 | | 0.05 | | |
| 222 | | 0.03 | | |
| 226 | M.S. + T.C. | 0.04 | 0.04 | |
| 227 | | 0.08 | 0.08 | |
| 228 | | 0.07 | 0.07 | |
| Maximum permitted (FFP1) | | 20 | | Pass |
| Maximum permitted (FFP2) | | 6.0 | | Pass |
| Maximum permitted (FFP3) | | 1.0 | | Pass |

Paraffin oil:

| Specimen | Condition | Penetration (%) | | |
|--------------------------|-------------|-----------------|----------------------|------|
| | | After 3 minutes | Max. during exposure | |
| 214 | A.R. | 0.10 | | |
| 215 | | 0.08 | | |
| 216 | | 0.08 | | |
| 223 | S.W. | 0.12 | | |
| 224 | | 0.16 | | |
| 225 | | 0.28 | | |
| 229 | M.S. + T.C. | 0.22 | 0.32 | |
| 230 | | 0.16 | 0.19 | |
| 231 | | 0.27 | 0.33 | |
| Maximum permitted (FFP1) | | 20 | | Pass |
| Maximum permitted (FFP2) | | 6.0 | | Pass |
| Maximum permitted (FFP3) | | 1.0 | | Pass |

7.10 Compatibility with skin**Model ZH3161**

No problems were encountered during limited practical performance testing.

Ltd

Total inward leakage testing was not carried out.

NAs

The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify.

NAs**Model ZH3161V**

No problems were encountered during limited practical performance testing.

Ltd

No problems were encountered during total inward leakage testing.

Pass

The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify.

NAs**7.11 Flammability****Model ZH3161V**

Specimens 244 and 245 (A.R.) and 246 and 247 (T.C.) were tested. None of the specimens ignited.

Pass

7.12 Carbon dioxide content of the inhalation air**Model ZH3161****Pass**

| Specimen | CO ₂ (%) |
|-------------------|---------------------|
| 135 | 0.64 |
| 136 | 0.74 |
| 137 | 0.75 |
| Maximum permitted | 1.0 |

7.13 Head harness**Model ZH3161**

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance testing.

Ltd

The head harness was self-adjusting and there were no adverse comments regarding security following limited practical performance testing.

Ltd

Inward leakage testing was not carried out.

NAs**Model ZH3161V**

The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance and total inward leakage testing.

Ltd

The head harness was self-adjusting and there were no adverse comments regarding security following limited practical performance and total inward leakage testing.

Ltd

The product satisfied the total inward leakage requirements. See 7.9.1 for results.

Pass**7.14 Field of vision****Model ZH3161**

There were no adverse comments following limited practical performance tests.

Ltd**Model ZH3161V**

There were no adverse comments following limited practical performance tests.

Ltd**7.15 Exhalation valve****Model ZH3161V**

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

Pass

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

Pass

The product satisfied leakage requirements as FFP2. See 7.9 for results.

Pass

There were no observed problems when assessing operation after high exhalation flow. See 7.16 for results.

Pass

The valve housing withstood 10N applied for 10s. Specimens 232 (A.R.), 233 (T.C.) and 234 (M.S.) were tested.

Pass

7.16 Breathing resistance

Model ZH3161

Ltd

| Specimen | Condition | Inhalation resistance (mbar) | | Exhalation resistance (mbar) |
|-------------------|-----------|------------------------------|-------------|------------------------------|
| | | At 30 l/min | At 95 l/min | At 160 l/min |
| 111 | A.R. | Not requested | | 2.30 |
| 112 | | | | 2.33 |
| 113 | | | | 2.19 |
| 117 | T.C. | Not requested | | 2.28 |
| 118 | | | | 2.26 |
| 119 | | | | 2.11 |
| 121 | S.W. | Not requested | | 2.08 |
| 122 | | | | 2.30 |
| 151 | | | | 2.24 |
| Maximum permitted | | | | 3.0 |

Model ZH3161V

| Specimen | Condition | Inhalation resistance (mbar) | | Exhalation resistance (mbar) |
|--------------------------|-------------|------------------------------|-------------|------------------------------|
| | | At 30 l/min | At 95 l/min | At 160 l/min |
| 211 | A.R. | 0.59 | 1.91 | 1.88 |
| 212 | | 0.53 | 1.74 | 1.80 |
| 213 | | 0.51 | 1.76 | 1.86 |
| 217 | T.C. | 0.47 | 1.60 | 1.57 |
| 218 | | 0.52 | 1.73 | 1.74 |
| 219 | | 0.51 | 1.70 | 1.72 |
| 220 | S.W. | 0.49 | 1.61 | 1.71 |
| 221 | | 0.50 | 1.70 | 1.48 |
| 222 | | 0.49 | 1.71 | 1.69 |
| 238 | A.R. + F.C. | 0.54 | 1.81 | 1.88 |
| 239 | T.C. + F.C. | 0.54 | 1.73 | 1.79 |
| 240 | | 0.56 | 1.89 | 2.06 |
| Maximum permitted (FFP1) | | 0.6 | 2.1 | 3.0 |
| Maximum permitted (FFP2) | | 0.7 | 2.4 | 3.0 |
| Maximum permitted (FFP3) | | 1.0 | 3.0 | 3.0 |

Pass

Pass

Pass

7.18 Demountable parts**Model ZH3161V**

No demountable parts were used.

NAP**9 Marking****Both models****9.1 Packaging**

The specimens were submitted in plastic bags inside a large cardboard box.

The marking on the packaging was clear and durable.

Pass

The markings required by the Standard were assessed as follows.

9.1.1 The manufacturer's identification was not present.

Fail

9.1.2 Type identification was marked.

Pass

9.1.3 The classification was not given.

Fail

9.1.4 The number and year of the standard were not given.

Fail

9.1.5 The end of shelf life was not given.

Fail

9.1.6 Neither the required statement nor pictogram relating to manufacturer's information was present.

Fail

9.1.7 The recommended storage requirements were not given.

Fail

9.1.8 The letter "D" was neither appropriate nor marked.

NAP**9.2 Particle filtering half mask**

The particle filtering half mask was not marked.

Fail**10 Information to be supplied by the manufacturer**

The instructions to users have been assessed as detailed below, with reference only to the relevant requirements of the Standard.

INSPEC Testing Services has not assessed these instructions with respect to claims made by the manufacturer outside of the requirements of the Standard, and therefore accepts no responsibility for the legitimacy of any such claims.

The information specified by the Standard was assessed as follows.

10.1 The information did not accompany smallest package, an example copy was sent.

Fail

10.2 Were in the official language (English).

Pass

10.3 Contained all necessary information for trained and qualified persons apart from;-

Pass

- colour codes were neither used or explained;

NAP

- maintenance information was not given, the mask was designated single use;

NAP

10.4 Were clear and comprehensible.

Pass

10.5 Required warnings were given against various problems likely to be encountered.

Pass

10.6 Discard information was provided.

Pass

10.7 The product was not marked with R or NR, manufacturer to certify regarding reuse of the device.

NAs

Estimates of the uncertainty of measurement

| Clause | Test | Uncertainty |
|--------|---|----------------|
| 7.4 | Packaging | Not Applicable |
| 7.5 | Material | See Note 1 |
| 7.6 | Cleaning and disinfecting | Not Applicable |
| 7.7 | Practical performance | See Note 1 |
| 7.8 | Finish of parts | Not Applicable |
| 7.9.1 | Total inward leakage | $\pm 4.7\%$ |
| 7.9.2 | Penetration of filter material - Sodium chloride | $\pm 4.8\%$ |
| 7.9.2 | Penetration of filter material - Paraffin oil | $\pm 4.2\%$ |
| 7.10 | Compatibility with skin | Not Applicable |
| 7.11 | Flammability | See Note 1 |
| 7.12 | CO ₂ content of the inhalation air | $\pm 4.0\%$ |
| 7.13 | Head harness | Not Applicable |
| 7.14 | Field of vision | See Note 1 |
| 7.15 | Exhalation valve(s) | See Note 1 |
| 7.16 | Breathing resistance | $\pm 2.1\%$ |
| 7.17.2 | Breathing resistance after clogging | $\pm 3.9\%$ |
| 7.17.3 | Filter penetration after clogging - Sodium chloride | $\pm 4.7\%$ |
| 7.17.3 | Filter penetration after clogging - Paraffin oil | $\pm 4.1\%$ |
| 7.18 | Demountable parts | Not Applicable |

Note 1 The acceptance criterion for this test is a straightforward “Pass/Fail”, rather than a numerical value. Consequently, as there is no value to be reported, uncertainty has not been reported either.

Note 2 The uncertainty value is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which provides for a confidence level of approximately 95%. Values expressed as a percentage (%) are relative.

It should be noted that the above values have not been taken into account when making assessment to the pass/fail criteria.