TEST REPORT

EN 149:2001+A1:2009

Respiratory protective devices-filtering half masks to protect against particles-requirements,testing,marking

For

WENZHOU MEIYI MEDICAL DEVICE CO., LTD

HENGJIE INDUSTRIAL,XIANJIANG STREET,RUIAN,WENZHOU ,ZHEJIANG ,CHINA

Model: MY-002

March 30, 2020

This Report Concerns:	**Equipment Type:**
☒ Original Report	KN95 MASK

Test Engineer:	Eric/
Report Number:	TH20CR-331S
Test Date:	March 23 - 29, 2020
Reviewed By:	Prince/
Approved By:	Prince/
Prepared By:	**Shenzhen Tian Hai Test Technology Co.,Ltd.** 4F, A3 BLDG, The Silicon Valley Power intelligent terminal industrial park, Guanlan street, Longhua district, Shenzhen Tel: +86-755-86615100 Fax:+86-755-86615105

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 Tian Hai Test Technology Co,.Ltd.

TEST REPORT

EN 149:2001+A1:2009

respiratory protective devices-filtering half masks to protect against particles-requirements,testing,marking

Report		
Report reference No.	:	TH20CR-331S
Tested by (+signature)	:	Eric
Reviewed by (+signature)	:	Prince
Approved by (+signature)	:	Prince
Date of issue	:	March 30, 2020
Testing laboratory		
Name	:	**Shenzhen Tian Hai Test Technology Co.,Ltd.**
Address	:	4F, A3 BLDG, The Silicon Valley Power intelligent terminal industrial park, Guanlan street, Longhua district, Shenzhen.
Test location	:	Same as above
Client		
Name	:	**WENZHOU MEIYI MEDICAL DEVICE CO., LTD**
Address	:	HENGJIE INDUSTRIAL,XIANJIANG STREET,RUIAN,WENZHOU ,ZHEJIANG ,CHINA
Test specification		
Standard	:	EN 149:2001+A1:2009
Non-standard test method	:	N.A.
Test item		
Description	:	**KN95 MASK**
Model and or type reference	:	MY-002
Trademark	:	--
Manufacturer	:	**WENZHOU MEIYI MEDICAL DEVICE CO., LTD**
Address	:	HENGJIE INDUSTRIAL,XIANJIANG STREET,RUIAN,WENZHOU ,ZHEJIANG ,CHINA
Note	:	--.

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Test case verdicts

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

Test item does meet the requirement : P(Pass)

Test item does not meet the requirement : F(Fail)

General remarks:

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

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

Attachment include:
Appendix for photo

Remarks:
Copy of the marking plate

Product: KN95 MASK
Model: MY-002 Classification: FFP2

CE

EN 149:2001+A1:2009
WENZHOU MEIYI MEDICAL DEVICE CO., LTD
HENGJIE INDUSTRIAL,XIANJIANG STREET,RUIAN,WENZHOU ,ZHEJIANG ,CHINA

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EN 149:2001+A1:2009			
Clause	**Requirement Test**	**Result**	**Verdict**
4	**Description**		P
	A particle filtering half mask covers the nose and mouth and the chin		P
	These devices are designed to protect against both solid and liquid aerosols		P
5	**Classification**		P
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage.There are three classes of devices:FFP1,FFP2 and FFP3.	FFP2	P
6	**Designation**		P
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner		P
	Particle filtering half mask EN149,year of publication, classification,option(where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask		P
7	**Requirements**		P
7.1	General		P
7.2	Nominal values and tolerances		P
	Except for temperature limits,values which are not stated as maxima or minima shall be subject to a tolerance of ± 5%.	All within ± 5%	P
	Unless other wise specified,the ambient temperature for testing shall be(16-32)°C,and the temperature limits shall be subject to an accuracy of±1°C	23.8°C	P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Complied	P
7.4	Packaging		P
	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. Testing shall be done in accordance with 8.2.	Complied	P
7.5	Material		P
	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.	Complied	P
	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.		P
	Three particle filtering half masks shall be tested.	Complied	P
	When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.		P
	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.		P

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EN 149:2001+A1:2009			
Clause	**Requirement Test**	**Result**	**Verdict**
	Testing shall be done in accordance with 8.2.		P
7.6	Cleaning and disinfecting		N/A
	If the particle filtering half mask is designed to be re-usable,the materials used shall with stand the cleaning and disinfecting agent sand procedures to be specified by the manufacturer	Not re-usable	N/A
	Testing shall be done in accordance with 8.4 and 8.5.		N/A
7.7	Practical performance		P
7.8	Finish of parts		P
	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	No sharp edges or burrs	P
7.9	Leakage		P
7.9.1	Total in ward leakage		P
	The total in ward leakage consists of three components:face seal leakage,exhalation valve leakage and filter penetration		P
	For particle filtering half masks fitted in accordance with the manufacturer's information,at least 46 out of the 50 individual exercise results for total inward leakage shall be not greater than: 25% for FFP1,11% for FFP2,5% for FFP3	9.2%	P
	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	6.2%	P
	Testing shall be done in accordance with 8.5.		P
7.9.2	Penetration of filter material		P
7.10	Compatibility with skin		P
	Materials shall not be known to be likely to cause irritation or any other adverse effect to health	Complied	P
	Testing shall be done in accordance with 8.4 and 8.5.		P
7.11	Flammability		P
	When test , the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame	Burn time:3.1s	P
7.12	Carbon dioxide content of the inhalation air		P
7.13	Head harness		P
7.14	Field of vision		P
7.15	Exhalation valve(s)		N/A
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.		N/A
	Testing shall be done in accordance with 8.2 and 8.9.1.		N/A
	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.	No exhalation valve	N/A
	Testing shall be done in accordance with 8.2.		N/A

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<table>
<tr><th colspan="4">EN 149:2001+A1:2009</th></tr>
<tr><th>Clause</th><th>Requirement Test</th><th>Result</th><th>Verdict</th></tr>
<tr><td></td><td>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.</td><td></td><td>N/A</td></tr>
<tr><td></td><td>Testing shall be done in accordance with 8.3.4.</td><td></td><td>N/A</td></tr>
<tr><td></td><td>When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.</td><td></td><td>N/A</td></tr>
<tr><td></td><td>Testing shall be done in accordance with 8.8.</td><td></td><td>N/A</td></tr>
<tr><td>7.16</td><td>Breathing resistance</td><td></td><td>P</td></tr>
<tr><td></td><td>The breathing resistance shall meet the requirement s of table 2
Table 2 — Breathing resistance
<table>
<tr><td>Classification</td><td colspan="3">Maximum permitted resistance (mbar)</td></tr>
<tr><td></td><td colspan="2">inhalation</td><td>exhalation</td></tr>
<tr><td></td><td>30 l/min</td><td>95 l/min</td><td>160 l/min</td></tr>
<tr><td>FFP1</td><td>0,6</td><td>2,1</td><td>3,0</td></tr>
<tr><td>FFP2</td><td>0,7</td><td>2,4</td><td>3,0</td></tr>
<tr><td>FFP3</td><td>1,0</td><td>3,0</td><td>3,0</td></tr>
</table></td><td>30l/min: 0.7mbar
95l/min: 2.3mbar
160l/min: 2.7mbar</td><td>P</td></tr>
<tr><td>7.17</td><td>Clogging</td><td></td><td>P</td></tr>
<tr><td>7.17.2</td><td>Breathing resistance</td><td></td><td>P</td></tr>
<tr><td>7.17.2.1</td><td>Valved particle filtering half masks</td><td></td><td>P</td></tr>
<tr><td></td><td>After clogging the inhalation resistances shall not exceed--
FFP1：4 mbar，FFP2：5 mbar，FFP3：7 mbar</td><td>4.6mbar</td><td>P</td></tr>
<tr><td></td><td>At 95l/min continuous flow</td><td></td><td>P</td></tr>
<tr><td></td><td>The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.</td><td>1.7mbar</td><td>P</td></tr>
<tr><td>7.17.2.2</td><td>Valveless particle filtering half masks</td><td></td><td>N/A</td></tr>
<tr><td></td><td>After clogging the inhalation resistances shall not exceed--
FFP1：3 mbar，FFP2：4 mbar，FFP3：5 mbar</td><td>3.2 mbar</td><td>N/A</td></tr>
<tr><td></td><td>At 95l/min continuous flow</td><td></td><td>N/A</td></tr>
<tr><td>7.17.3</td><td>Penetration of filter material</td><td></td><td>P</td></tr>
<tr><td>7.18</td><td>Demountable parts</td><td></td><td>P</td></tr>
<tr><td>8</td><td>Testing</td><td></td><td>P</td></tr>
<tr><td>9</td><td>Marking</td><td></td><td>P</td></tr>
<tr><td>9.1</td><td>Packaging</td><td></td><td>P</td></tr>
<tr><td></td><td>The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.</td><td>Complied</td><td>P</td></tr>
<tr><td>9.1.1</td><td>The name, trademark or other means of identification of the manufacturer or supplier.</td><td>WENZHOU MEIYI MEDICAL DEVICE CO., LTD</td><td>P</td></tr>
<tr><td>9.1.2</td><td>Type-identifying marking.</td><td>MY-002</td><td>P</td></tr>
<tr><td>9.1.3</td><td>Classification</td><td>FFP2</td><td>P</td></tr>
</table>

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Clause	**Requirement Test**	**Result**	**Verdict**
9.1.4	The number and year of publication of this European Standard.	EN 149:2001+A1:2009	P
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.	2021/12	P
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.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram		P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		N/A
	This letter shall follow the classification marking preceded by a single space.		P
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	WENZHOU MEIYI MEDICAL DEVICE CO., LTD	P
9.2.2	Type-identifying marking.	MY-002	P
9.2.3	The number and year of publication of this European Standard.	EN149:2001+A1:2009	P
9.2.4	Classification	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance.		N/A
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P
10	**Information to be supplied by the manufacturer**		P
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package.		P
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.		P
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on		P
	-- application/limitations;		P
	-- the meaning of any colour coding;		P
	-- checks prior to use;		P
	-- donning, fitting;		P
	-- use;		P
	-- maintenance (e.g. cleaning, disinfecting), if applicable;		P
	-- storage;		P
	-- the meaning of any symbols/pictograms used of the equipment.		P

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Clause	**Requirement Test**	**Result**	**Verdict**
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Complied	P
10.5	Warning shall be given against problems likely to be encountered, for example:		P
	--fit of particle filtering half mask (check prior to use);		P
	--it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;		P
	--air quality (contaminants, oxygen deficiency);		P
	--use of equipment in explosive atmosphere.		P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P
10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.		P

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EUT PHOTOGRAPHS

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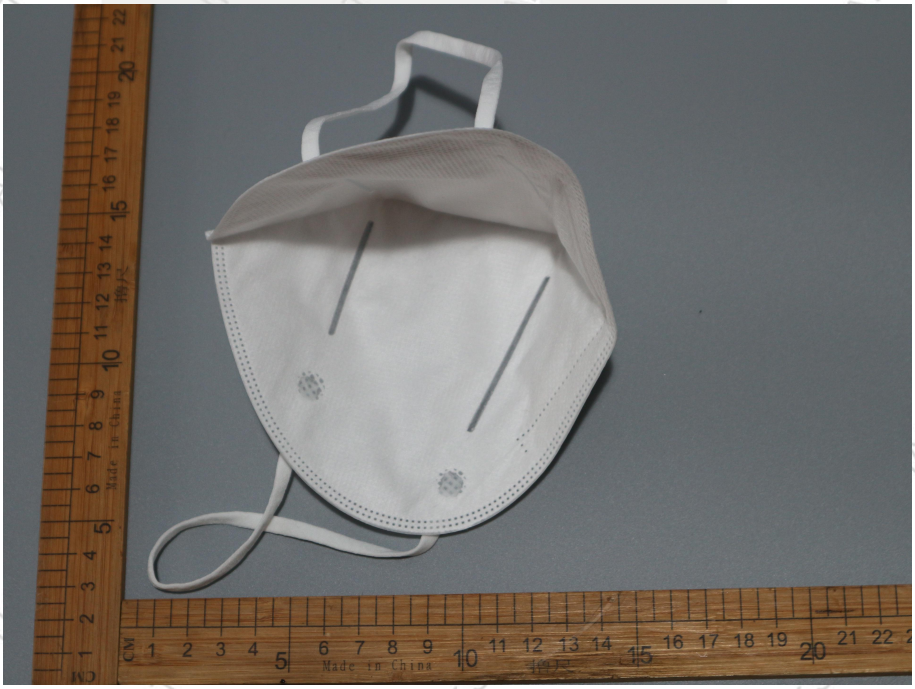

********** END OF THE REPORT **********

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China National Accreditation Service for Conformity Assessment

LABORATORY ACCREDITATION CERTIFICATE

(Registration No. CNAS L5885)

Shenzhen Tianhai Test Technology Co., Ltd.

(Legal Entity: Shenzhen Tianhai Test Technology Co., Ltd.)

4B/F., Building A3, The Silicon Valley Power Intelligent Terminal Industrial Park, Guanlan Street, Longhua District, Shenzhen, Guangdong, China

is accredited in accordance with ISO/IEC 17025: 2017 General Requirements for the Competence of Testing and Calibration Laboratories(CNAS-CL01 Accreditation Criteria for the Competence of Testing and Calibration Laboratories) for the competence to undertake the service described in the schedule attached to this certificate.

The scope of accreditation is detailed in the attached schedule bearing the same registration number as above. The schedule forms an integral part of this certificate.

Effective Date：2019-01-22

Expiry Date：2025-01-21

Signed on behalf of China National Accreditation Service for Conformity Assessment

China National Accreditation Service for Conformity Assessment(CNAS) is authorized by Certification and Accreditation Administration of the People's Republic of China (CNCA) to operate the national accreditation schemes for conformity assessment. CNAS is a signatory of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) and the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (APLAC MRA).

The validity of the certificate can be checked on CNAS website at http://www.cnas.org.cn/english/findanaccreditedbody/index.shtml