



Certificate

ICR Polska/CE/V/00R0E44

Name and address of certificate owner: Tianjin Benmo Medical Devices Co., Ltd. 1F, Block 1, D2-B-1, Xiqing Xuefu Industrial zone west, No. 2 Xuefu West Road, Xiqing District, Tianjin

Name and address of manufacturer: Tianjin Benmo Medical Devices Co., Ltd. 1F, Block 1, D2-B-1, Xiqing Xuefu Industrial zone west, No. 2 Xuefu West Road, Xiqing District, Tianjin

Product name: Self-priming filter-type replaceable respirator

Product types: KN95

Product trademark: DND

- This certificate confirms that the product meets the requirements of the following standard
- The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Regulation 2016/425**

EN 149:2001+A1:2009

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.: PPE01P200309008

Test conducted by: STS Testing (Shenzhen) Technology Co., Ltd

Certificate issue date: 02.04.2020

Expiration date: 01.04.2025

NOTE:

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued

Certificate modifications: N/A

ICR Polska Co. Ltd.
Plac Przymierza 6
03-944 Warsaw
www.icrpolska.com
e-mail: icrpolska@icrga.com

Dir

Warsaw, 02.04.2020





TEST REPORT

EN 149:2001+A1: 2009

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

For

Tianjin Benmo Medical Equipment Co., Ltd.

D2-B1, Xuefu Industrial zone west, No. 2 Xuefu Road, Xiqing District, Tianjin

Model: BM-01,BM-02

March 23, 2020

This Report Concerns: <input checked="" type="checkbox"/> Original Report	Equipment Type: KN95 Protective mask
Test Engineer:	Eric/
Report Number:	TH20CR-297S
Test Date:	March 18 - 22,2020
Reviewed 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

not



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-297S
Tested by (+signature)	: Eric
Reviewed by (+signature)	: Prince
Approved by (+signature)	: Prince
Date of issue	: March 23, 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	: Tianjin Benmo Medical Equipment Co., Ltd.
Address	: D2-B1, Xuefu Industrial zone west, No. 2 Xuefu Road, Xiqing District, Tianjin.
Test specification	
Standard	: EN 149:2001+A1:2009
Non-standard test method	: N.A.
Test item	
Description	: KN95 Protective mask
Model and or type reference	: BM-01,BM-02
Trademark	: --
Rating	: --
Manufacturer	: Tianjin Benmo Medical Equipment Co., Ltd.
Address	: D2-B1, Xuefu Industrial zone west, No. 2 Xuefu Road, Xiqing District, Tianjin.
Note	: --



Test case verdicts

Test case does not apply to the test object : N (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
Appendix for circuit
Appendix for Manual

Remarks:

Copy of the marking plate

Product:KN95 Protective mask

Model: BM-01,BM-02

Classification: FFP2



EN 149:2001+A1:2009

Tianjin Benmo Medical Equipment Co., Ltd.

**D2-B1, Xuefu Industrial zone west, No. 2 Xuefu Road, Xiqing
District, Tianjin.**



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
	Particle filtering half mask EN 149:2001+A1:2009 FFP1 NR D		N/A
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 $\pm 5\%$.	All within $\pm 5\%$	P
	Unless otherwise specified, the ambient temperature for testing shall be $(16-32)^{\circ}\text{C}$, and the temperature limits shall be subject to an accuracy of $\pm 1^{\circ}\text{C}$	25.2°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



EN 149:2001+A1:2009			
Clause	Requirement Test	Result	Verdict
	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
	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 withstand the cleaning and disinfecting agent and 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 inward leakage		P
	The total inward 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%	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	7%	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:3s	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)		P
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.		P
	Testing shall be done in accordance with 8.2 and 8.9.1.		P



EN 149:2001+A1:2009																													
Clause	Requirement Test	Result	Verdict																										
	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																										
	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.		N/A																										
	Testing shall be done in accordance with 8.3.4.		N/A																										
	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.		N/A																										
	Testing shall be done in accordance with 8.8.		N/A																										
7.16	Breathing resistance		P																										
	<table border="1"> <thead> <tr> <th colspan="4">Table 2 — Breathing resistance</th></tr> <tr> <th rowspan="3">Classification</th><th colspan="3">Maximum permitted resistance (mbar)</th></tr> <tr> <th colspan="2">Inhalation</th><th>exhalation</th></tr> <tr> <th>30 l/min</th><th>95 l/min</th><th>160 l/min</th></tr> </thead> <tbody> <tr> <td>FFP1</td><td>0.8</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> </tbody> </table> <p>The breathing resistance shall meet the requirements of table 2</p>	Table 2 — Breathing resistance				Classification	Maximum permitted resistance (mbar)			Inhalation		exhalation	30 l/min	95 l/min	160 l/min	FFP1	0.8	2.1	3.0	FFP2	0.7	2.4	3.0	FFP3	1.0	3.0	3.0	Meet FFP2 requirements	P
Table 2 — Breathing resistance																													
Classification	Maximum permitted resistance (mbar)																												
	Inhalation		exhalation																										
	30 l/min	95 l/min	160 l/min																										
FFP1	0.8	2.1	3.0																										
FFP2	0.7	2.4	3.0																										
FFP3	1.0	3.0	3.0																										
7.17	Clogging		P																										
7.17.2	Breathing resistance		P																										
7.17.2.1	Valved particle filtering half masks		P																										
	After clogging the inhalation resistances shall not exceed-- FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar	4.5 mbar	P																										
	At 95l/min continuous flow		P																										
	The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.	1.8mbar	P																										
7.17.2.2	Valveless particle filtering half masks		N/A																										
	After clogging the inhalation resistances shall not exceed-- FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar	3.3 mbar	N/A																										
	At 95l/min continuous flow		N/A																										
7.17.3	Penetration of filter material		P																										
7.18	Demountable parts		P																										
8	Testing		P																										
9	Marking		P																										
9.1	Packaging		P																										
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied	P																										



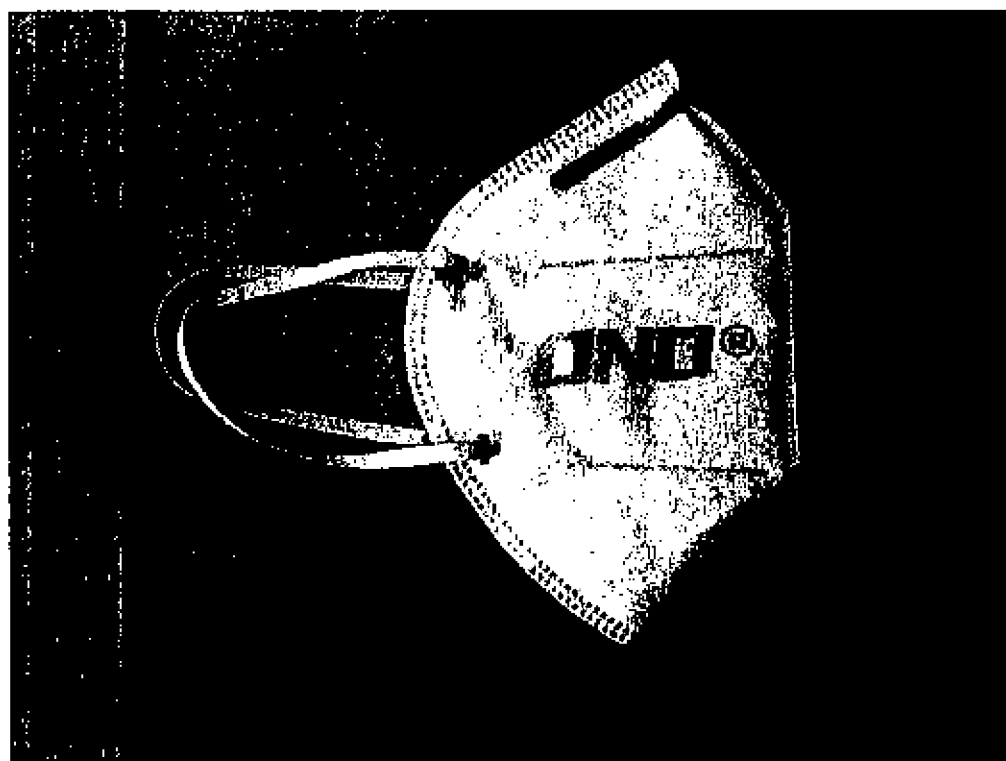
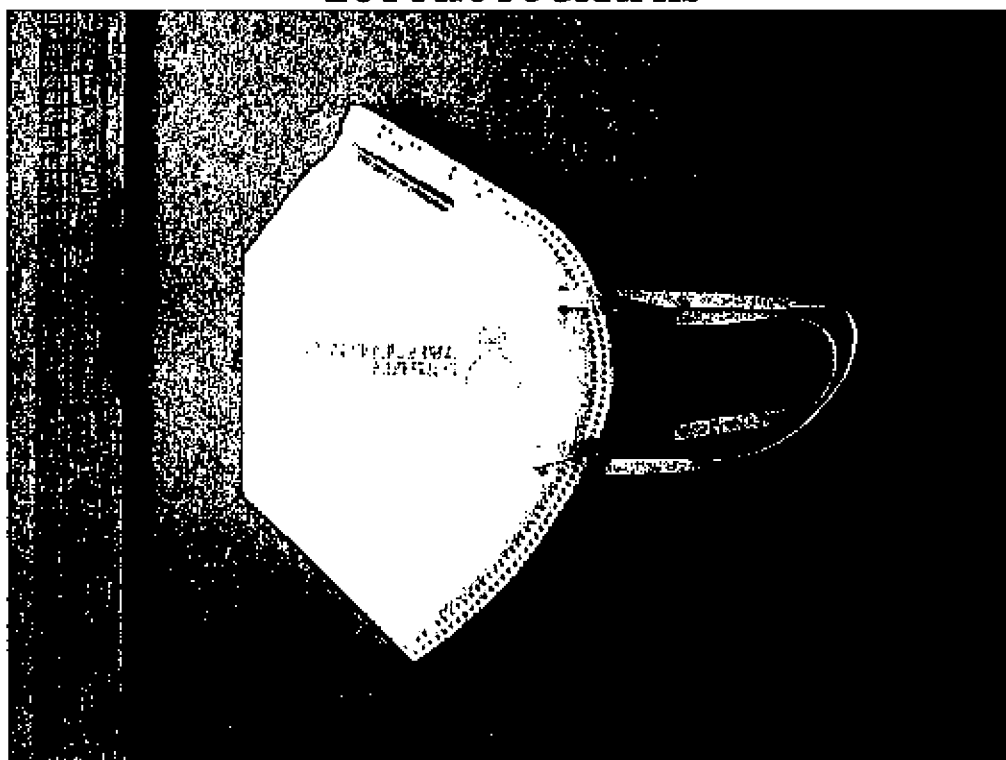
EN 149:2001+A1:2009			
Clause	Requirement Test	Result	Verdict
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	Tianjin Benmo Medical Equipment Co., Ltd.	P
9.1.2	Type-identifying marking.	BM-01,BM-02	P
9.1.3	Classification	FFP2	P
9.1.4	The number and year of 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".		P
	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.	Tianjin Benmo Medical Equipment Co., Ltd.	P
9.2.2	Type-identifying marking.	BM-01,BM-02	P
9.2.3	The number and year of publication of this European Standard.	EN 149:2001+A1:2009	P
9.2.4	Classification	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance.		P
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

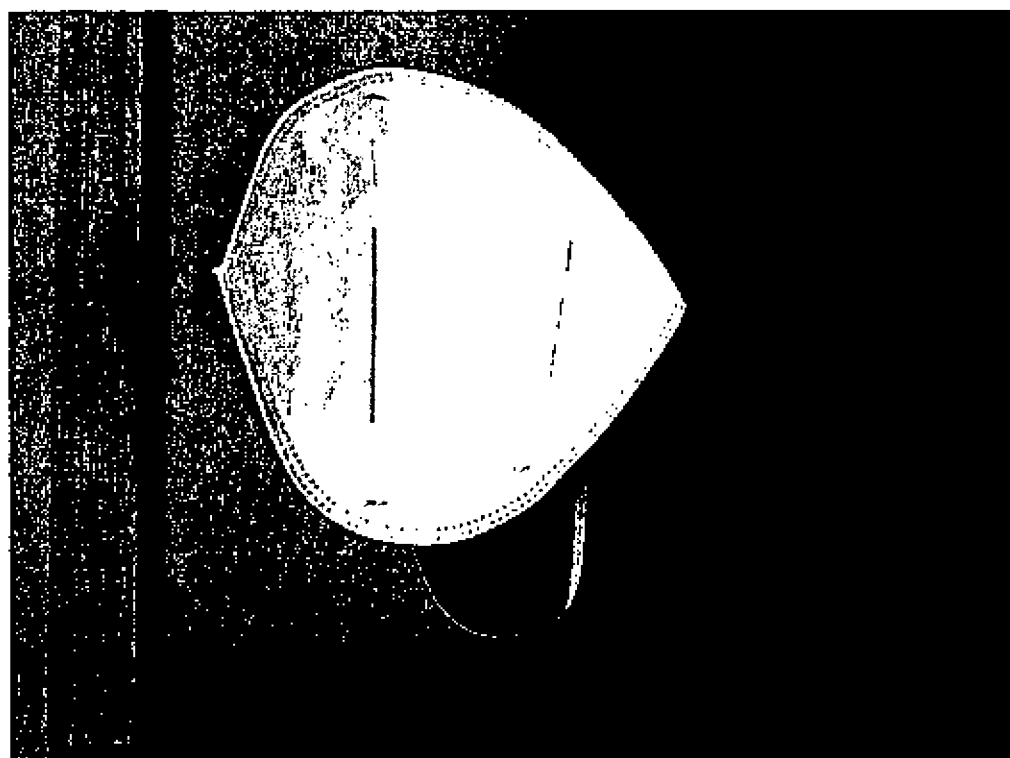
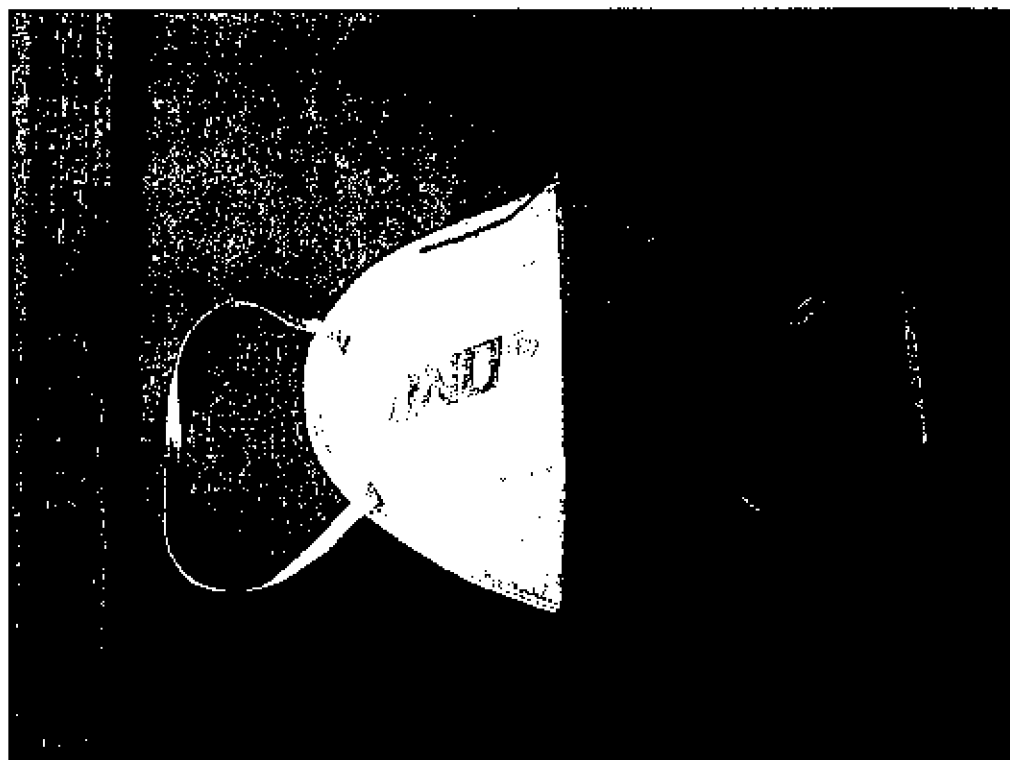


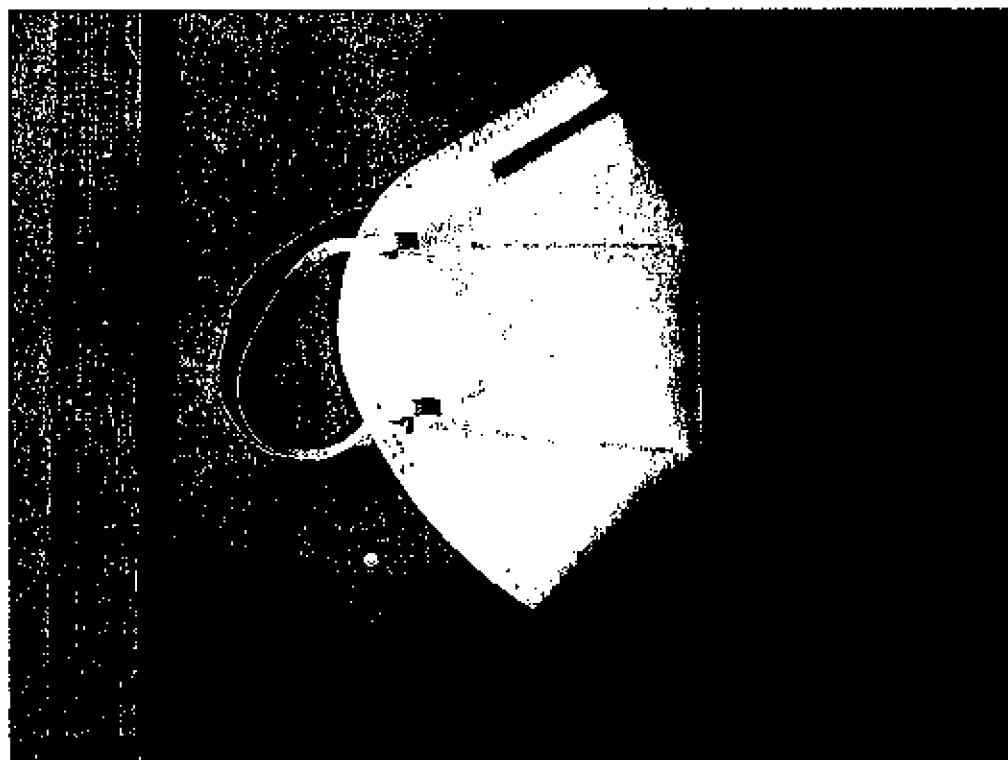
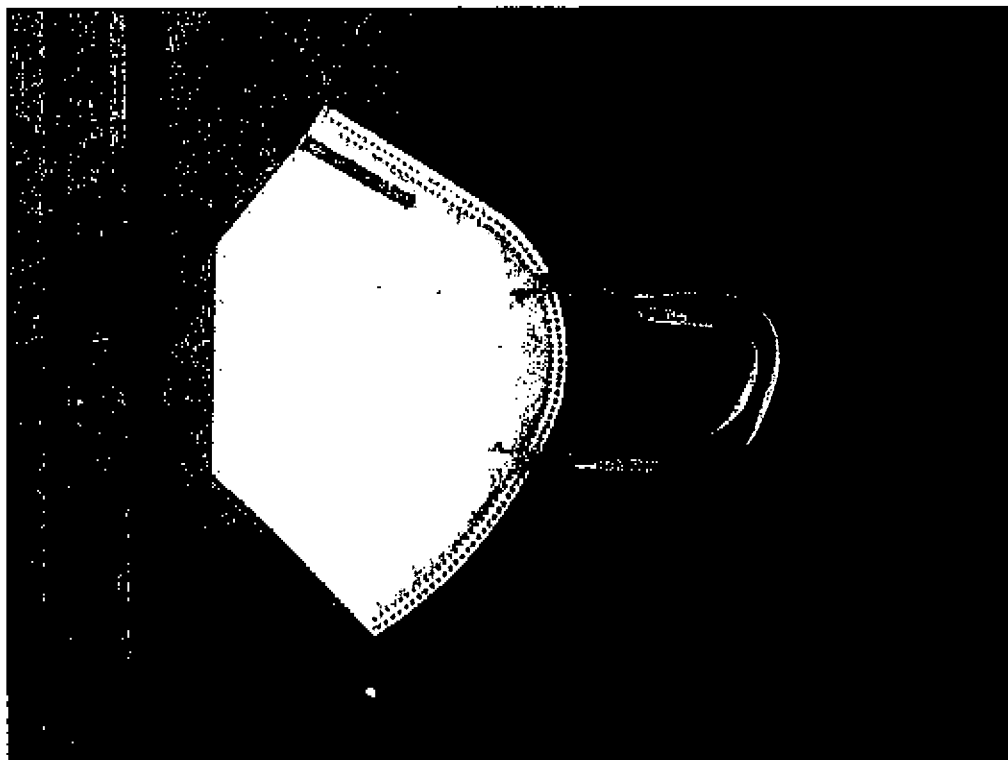
EN 149:2001+A1:2009			
Clause	Requirement Test	Result	Verdict
	-- use;		P
	-- maintenance (e.g. cleaning, disinfecting), if applicable;		P
	-- storage;		P
	-- the meaning of any symbols/pictograms used of the equipment.		P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, 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

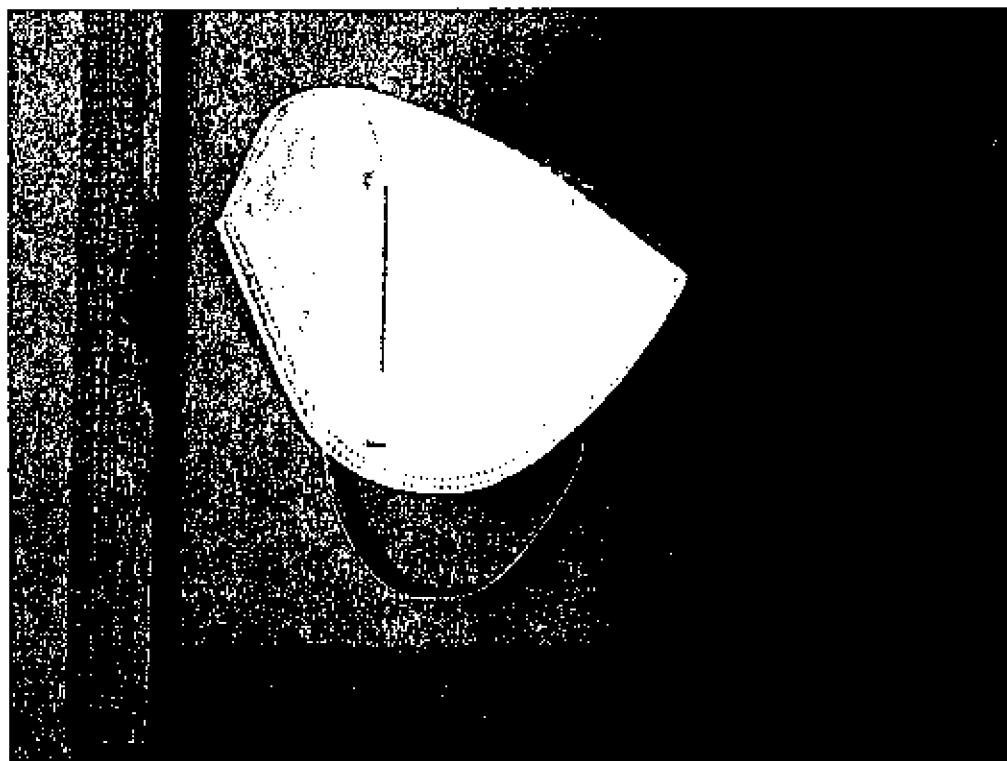
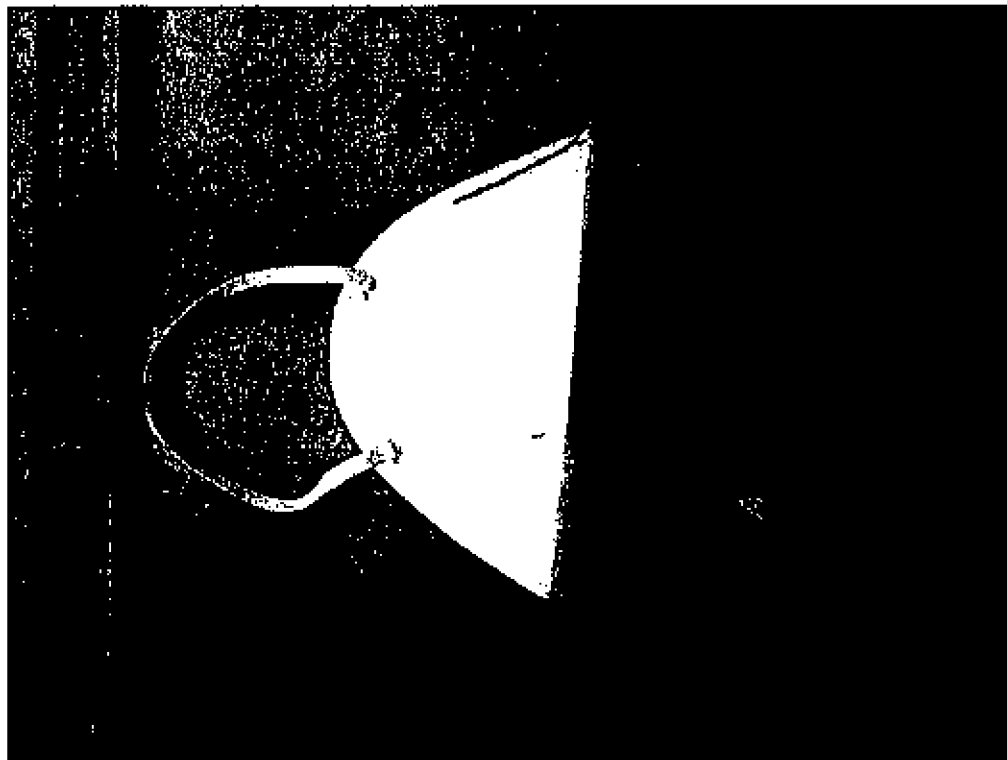


EUT PHOTOGRAPHS









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