TEST REPORT

EN 149:2001+A1:2009
Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Report reference No..... :	STS200314191301R
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Approved by (+ signature).....:	Hart Qiu
Date of issue.....:	Mar 24. 2020
Contents.....:	10 pages

Testing laboratory

Name.....:	Shenzhen Schbeder Technology Co., Ltd
Address.....:	6F, Meinian Building, Nanhai Rd, Nanshan District, Shenzhen, China
Testing location.....:	Same as above

Client

Name.....:	Changzhou Genebest Medical Technology Co. , Ltd
Address.....:	Xinchen Village,Lijia Town,Wujin District,Changzhou,Jiangsu

Test specification

Standard.....:	EN 149:2001+A1:2009
Test procedure.....:	Compliance with
Non-standard test method.....:	N/A

Test item Description.....:	Disposable Face Mask (non-medical)
Trademark.....:	JBS
Model and/or type reference.....:	JBS-001, JBS-002
Manufacturer.....:	Changzhou Genebest Medical Technology Co. , Ltd
Address.....:	Xinchen Village,Lijia Town,Wujin District,Changzhou,Jiangsu
Rating.....:	N/A

List of Attachments (including a total number of pages in each attachment):	
Summary of testing:	
Tests performed (name of test and test clause): Tests Full	**Testing location:** Shenzhen Schbeder Technology Co., Ltd 6F, Meinian Building, Nanhai Rd, Nanshan District, Shenzhen, China
Summary of compliance with National Differences: **List of countries addressed:** ☒ The product fulfils the requirements of EN 149:2001+A1:2009	

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

(Additional requirements for markings. See 1.7 NOTE)

As declared by the applicant the authorized EEA representative or importer was not decided at the time of application, but will be marked on the products before placing them on the market.

Note: According to ProdSG Art. 6 when placing the products on the market the authorized representative / importer within the European Economic Area (EEA) must be marked on the product if the manufacturer is not located within the EEA. Marking on the packaging is only acceptable if it is not possible to place such markings on the product.

General remarks:

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 Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

The tested sample(s) and the sample information are provided by the client.

These tests fulfill the requirements of standard ISO/IEC 17025.

When determining the test conclusion, the Measurement Uncertainty of test has been considered.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies)..... :	Same as applicant

General product information:

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Abbreviations used in the report:

- normal conditions	**N.C**.	- single fault conditions	**S.F.C**
- functional insulation	**OP**	- basic insulation	**BI**
- double insulation	**DI**	- supplementary insulation	**SI**
- between parts of opposite polarity	**BOP**	- reinforced insulation	**RI**

Indicate used abbreviations (if any)

EN 149:2001+A1			
Test Property	Test Method	Test Principle / Requirements	Test Result
Classification	EN 149:2001+A1:2009 Clause 5	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.	Pass. FFP1,FFP2,FFP3.
Designation	EN 149:2001+A1:2009 Clause 6	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner: Particle filtering half mask EN 149, 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).	Pass. re-useable particle filtering half mask
Nominal values and tolerances	EN 149:2001+A1:2009 Clause 7.2	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) ° C, and the temperature limits shall be subject to an accuracy of ± 1 ° C.	Pass. +5℃ to +38℃.
Visual inspection	EN 149:2001+A1:2009 Clause 7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Pass
Packaging	EN 149:2001+A1:2009 Clause 7.4& Clause 8.2	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. The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.	Pass
Material	EN 149:2001+A1:2009 Clause 7.5& Clause 8.3	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 ° C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air shall be saturated at (37 ± 2) ° C at the mouth of the dummy head. In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be inclined so that the water runs away from the mouth and is collected in a trap. Expose the particle filtering half masks to the	Pass. None of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. The particle filtering half mask shall not collapse.

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		following thermal cycle: a) for 24 h to a dry atmosphere of (70 ± 3) °C; b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning shall be carried out in a manner which ensures that no thermal shock occurs.	
Cleaning and disinfecting	EN 149:2001+A1:2009 Clause 7.6& Clause 8.4& Clause 8.5	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. Testing shall be done in accordance with 8.4 and 8.5. 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. Testing shall be done in accordance with 8.11.	Pass
Practical performance	EN 149:2001+A1:2009 Clause 7.7& Clause 8.4	Walking test The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min. Work simulation test The individual activities shall be arranged so that sufficient time is left for the comments prescribed. a) walking on the level with headroom of (1,3 ± 0,2) m for 5 min; b) crawling on the level with headroom of (0,70 ± 0,05) m for 5 min; c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned. The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. This shall be done 20	Pass. The particle filtering half mask could undergo practical performance tests under realistic conditions.

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		times in 10 min.	
Finish of parts	EN 149:2001+A1:2009 Clause 7.8& Clause 8.2	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. Testing shall be done in accordance with 8.2.	Pass. No sharp edges and burrs.
Total inward leakage	EN 149:2001+A1:2009 Clause 7.9.1& Clause 8.5	1)walking for 2 min without head movement or talking; 2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min; 3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min; 4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min; 5)walking for 2 min without head movement or talking. The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other. $$P(\%)=\frac{C_2}{C_1}\times\left(\frac{t_{IN}+t_{EX}}{t_{IN}}\right)\times 100$$ where C1 is the challenge concentration C2 is the measured mean concentration in the breathing zone of the test subject tIN is the total duration of inhalation tEX is the total duration of exhalation	Total inward leakage is 7%.
Penetration of filter material	EN 149:2001+A1:2009 Clause 7.9.2	The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol. Testing of penetration, exposure and storage shall be done in accordance with EN 13274-7. The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1. Table 1 — Penetration of filter material Classification | (2) Maximum penetration of test aerosol (3) Sodium chloride test 95 l/min: % max. | Paraffin oil test 95 l/min: % max. FFP1: 20 | 20 FFP2: 6 | 6 FFP3: 1 | 1	Pass See the ANNEX I. The penetration of paraffin oil test is 0.94%. The penetration of sodium chloride test is 0.25%.

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		line and then fed into the exhaled air via a CO2 analyser. To measure the CO2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml. Measure the carbon dioxide content of the inhaled air and record continuously.	
Head harness	EN 149:2001+A1:2009 Clause 7.13	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 and be capable of maintaining total inward leakage requirements for the device.	Pass
Field of vision	EN 149:2001+A1:2009 Clause 7.14	The field of vision is acceptable if determined so in practical performance tests.	Pass
Exhalation valve(s)	EN 149:2001+A1:2009 Clause 7.15	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. 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 faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	Pass
Breathing resistance	EN 149:2001+A1:2009 Clause 7.16& Clause 8.9	Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continous flow 160 l/min. Use a suitable pressure transducer. Measure the exhalation resistance with the dummy head successively placed in 5 defined positions: - facing directly ahead - facing vertically upwards - facing vertically downwards	Pass. Inhalation resistance at 30 l/min:<0.6mbar. Inhalation resistance at 95 l/min:<2.1mbar. Exhalation resistance at 160 l/min: <3.0mbar.

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		- lying on the left side - lying on the right side Test the inhalation resistance at 30 l/min and 95 l/min continuous flow. The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2. **Table 2 — Breathing resistance** Classification | Maximum permitted resistance (mbar) | inhalation | exhalation 30 l/min | 95 l/min | 160 l/min FFP1 | 0,6 | 2,1 | 3,0 FFP2 | 0,7 | 2,4 | 3,0 FFP3 | 1,0 | 3,0 | 3,0	
Clogging	EN 149:2001+A1:2009 Clause 7.17& Clause 8.10	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m /h. Fit the sample particle filtering half mask in a leaktight manner to a dummy head or a suitable filter holder located in the dust chamber. Connect the breathing machine and humidifier to the sample and operate for the specified testing time. The concentration of dust in the test chamber may be measured by drawing air at 2 l/min through a sampling probe equipped with a pre-weighed, high efficiency filter (open face, diameter 37 mm) located near the test sample, as shown in Figure 10. Calculate the dust concentration from the weight of dust collected, the flow rate through the filter and the time of collection.	Pass. After clogging the inhalation resistances does not exceed 5 mbar at 95 l/min continuous flow; The exhalation resistance does not exceed 3 mbar at 160 l/min continuous flow.
Demountable parts	EN 149:2001+A1:2009 Clause 7.18	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Pass.

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ANNEX I The Paraffin Oil Test

Air Flow	Exhalation resistance(mm of H_20)	Penetration(%)
F 95.0	19.30	0.926
F 95.1	18.90	0.914
F 95.1	19.00	0.931
F 95.1	19.10	0.902
F 95.0	19.20	0.957
F 95.1	19.10	0.928
F 95.0	19.00	0.933
F 95.0	18.80	0.964
F 94.9	19.10	0.938
F 95.0	19.00	0.967
F 94.9	19.30	0.942
F 95.1	18.80	0.921
F 95.0	19.10	0.909
F 95.0	18.90	0.912
F 95.1	19.40	0.941
F 94.9	18.70	0.919
F 95.1	19.10	0.957
F 95.0	19.20	0.989
F 95.1	18.90	0.994
F 95.0	19.00	0.962

EN149: 2001+A2009 FFP2 standard : Air Flow = F95 , Penetration $\leqslant$ 1% , Exhalation resistance(mm of H_20) $\leqslant$ 24 .

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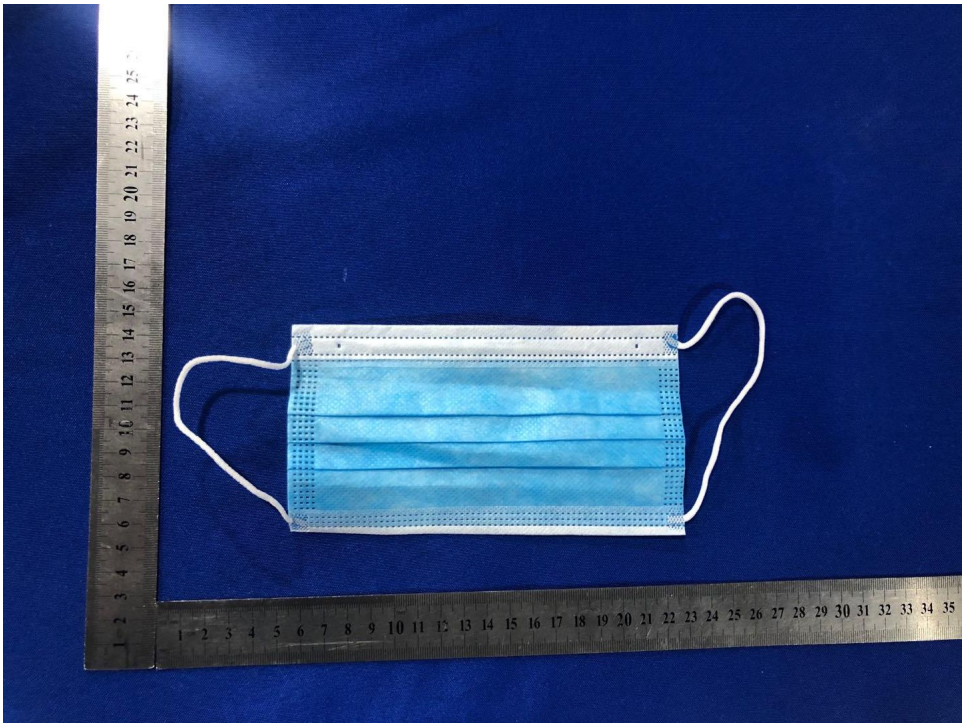

Photo 1

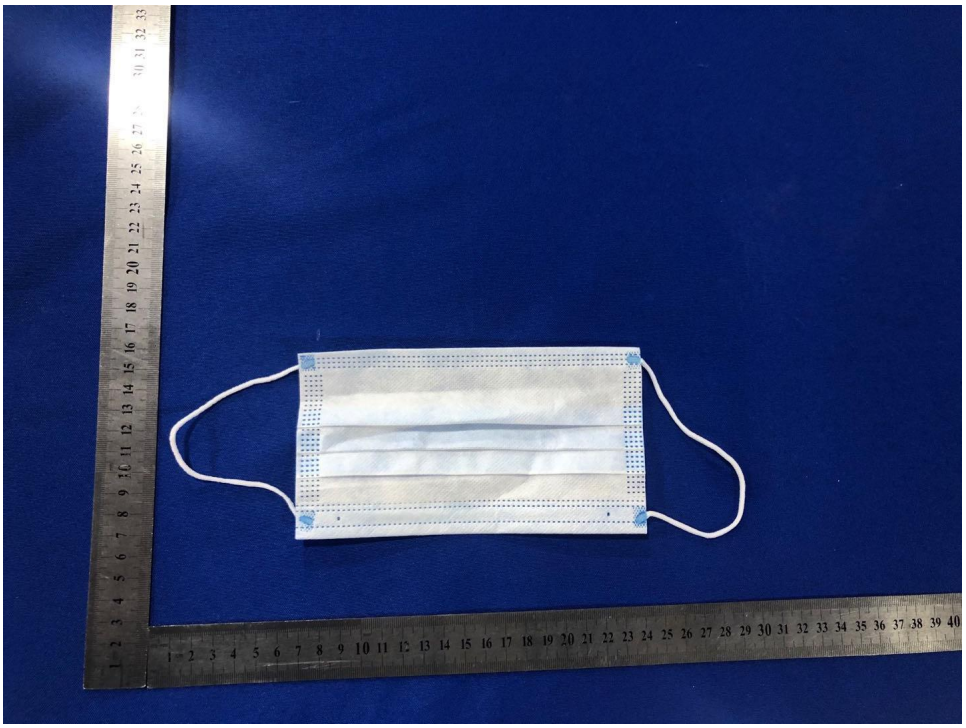

Photo 2

**********End Report**********