

REPORT OF SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

1. *Name and address of manufacturer*

Autómax Industrial Ltd.
No 75, Baowang Road, Gaoqiao Ind zone,
Ningbo, 315174,
China

2. *Identification of personal protective equipment:*

Filtering half masks to protect against particles
— 7020GD FFP2 NR D
— 7021GDV FFP2 NR D

EU- type examination certificate

ITT.43.56.6.3.244.PPE.2534
Issue II of 01 October 2019
Issued by: Institute of Textile Technologies
CERTEX Ltd

3. *Reference documents*

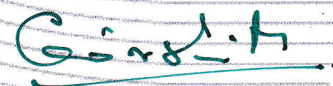
- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC;
- Harmonized standards:
 - EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

4. *Scope of checking:*

- A. Assessment of the product conformity with standard requirements and product type stipulated in the certificate of the EU-type examination specified in item 2 – examination of the samples taken during the checking procedure,
- B. Assessment of the production homogeneity – inspection at the place designated by manufacturer for verification of production homogeneity and results of the fabricated product tests.

5. *Date of checking:* 25 September 2019

Date of issue: 20 December, 2019
Expiry date: 19 December, 2020



Michał Górski
President of Board

INSTITUTE of TEXTILE TECHNOLOGIES

CERTEX Sp. z o.o. (Ltd.)

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NOTIFIED BODY № 2534

CONFORMITY ASSESSMENT BODY № AC 175



REPORT OF SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)

6. *Supervised contract:*
 – Contract No UE-5-2018-C2 of 18 December 2018
7. *Place of checking:*
 Automax Industrial Ltd.
 No 75, Baowang Road, Gaoqiao Ind zone,
 Ningbo, 315174,
 China
8. *ITT CERTEX representative:*
 Michal Gorski
9. *Representatives of supervised entity*
 Mr. Qiu – Owner
 Mr. Liu – Production chief manager
10. *Supervised product:*

<i>Name, type, model, symbol</i>	<i>No of EU-type examination certificate</i>	<i>Harmonized standard</i>
Filtering half masks to protect against particles – 7020GD FFP2 NR D – 7021GDV FFP2 NR D	ITT.43.56.6.3.244.PPE.2534 Issue II of 01 October 2019	EN 149:2001+A1:2009

11. *Course of checking:*

Supply system (assessment of suppliers, inspection of supplies)

The checking procedure included documents on the supplies of raw materials, their checking and storing. Automax Industrial Ltd buys basic raw materials and other indispensable additions for production from regular and reliable suppliers. Inspectors were presented with a list of 8 suppliers of the raw materials needed in the manufacturing process. Each lot of the raw material is supplemented with a bill of landing including a kind and quantity of material. Regarding the nonwoven fabrics, the info includes name, roll number and length, weight and color. Based on this data, a warehouse manager produces an internal document to record the reception of raw material. The basic raw material for production are nonwoven fabrics (composition: 100 % polypropylene, surface mass: 28 g/m² PP nonwoven (cover material), 100 g/m² PP nonwoven (bottom material), 45 g/m² PP (filter media material), 200 g/m² PP nonwoven (bottom material), white). Production chief manager measures/checks the surface mass and records findings in the registry of measurements. The last entry is of 23 September 2019 and includes the measurement conformity with the declared surface mass. The registry includes the following data: name of examined sample, date of examination, result of measurement and examined sample. A pair of scales and a punching tool are stored in the laboratory room.

Basic materials management (storage, preparation for production)

Textiles and additions used for manufacturing of the supervised products are stored in the conditions protecting them against moisture, temperature and damage. The shelves for nonwoven fabrics are marked with the names of nonwoven fabrics and internal numbers assigned for each raw material (item code). Each roll is packed in foil and marked with a label including manufacturer's name, name, color, number of current meters, raw material composition, surface mass of the nonwoven fabric and supply date. Additions are stored on the shelves, in cardboard boxes marked with the name, item code, color and manufacturer's name.

Technological process

Inspectors learnt about the process of production of the aforementioned goods, mode of checking and methods of assessment of the fabricated product quality. Manufacturer has all necessary technical and technological documentation for identification of products and kind of raw materials and components. This includes

- TECHNICAL DOCUMENTATIO No. FFP2/7020GD-7021GDV/PPE-Reg/2018

approved on 17 September 2018. Max Qiu, Owner, is responsible for the documentation approval.

Documentation on the course of production has been revised based on the order dated as of 22 August 2019 on the

half masks type 7020GD FFP2 NR D and 7021GDV FFP2 NR D. Production process is started by the Chief Manager of Production based on the client's order. The order document includes number and date of the client's order, quantity and types of ordered goods. Each material and addition has an individual number in the system. Based on this number, system specifies the demand for raw materials and additions and if they are out of store the Chief Manager of Production places an order to the supplier. Raw materials and additions are released from the warehouse and delivered to the department of production upon the confirmation on the order and this starts production.

Quality control and acceptance tests

All employees engaged at the process of production of the aforementioned goods are obligated to perform regular control checks of the correctness of performed activities and quality of manufactured products. Search for defects in the nonwoven fabrics is done during the process of cutting and connecting nonwoven fabrics. Control checks lie within responsibilities of the machine operator. Defective components are removed from the production process. Successive control checks are performed when a valve is attached, head harness and nose strap are connected with straps and when marking is put on. Employees have access to the product specification and pattern to ensure regular control of the correctness of workmanship, assembly and marking. Any defects found in materials or additions are reported in the control sheet. Fabricated products undergo control checks in the warehouse. A person responsible for these checks takes every tenth mask for 10000 manufactured products from a given lot, performs a quality check control and transfers to the internal laboratory. There the tests are conducted to assess the paraffin oil filtration efficacy in the device; breathing resistance and penetration of the filter material test machine marked as GDBRAPOFMTM, serial number NBJMLAB001, year of production 2017; airtightness of the valve in the device marked as Mask valve leakage test machine – symbol GDMVLTM, serial number NBJMLAB002, year of production: 2017. Entries made on 15 September 2019 in the test report with reference to the products under supervision. The test findings have confirmed compliance with requirements. Prior to packing into cardboard boxes, all the products are subject to the 100 % control check. The quality controller checks

- marking conformity with prescribed pattern,
- correctness of construction connections,
- correctness and finish of half masks,
- fastening of head harness, nose strap and valve,
- packaging and relevant information from manufacturer.

An order document is produced and packed in the production facility and then transferred to the warehouse of fabricated products by means of the in-factory transport. Information containing product name, order specification, manufacturer identity, product quantity is provided with signatures and date and handed over to the production chief manager.

After control check is performed, fabricated products are entered into warehouse to be prepared for sending to the client.

Marking, information from manufacturer

Marking and manufacturer's information attached to the packaging was assessed. A packaging containing 7020 GD FFP2 NR D and 7021 GDV FFP2 NR D half masks was randomly collected from the warehouse of fabricated goods to check marking and determine whether manufacturer's information complies with the specification. Declaration was signed by Mr. Max Qiu, the Owner, acting on behalf of the manufacturer, on 11 October 2018. Declaration is attached to each cardboard box containing herein products.

Fabricated products management (storage, packaging, transport)

Fabricated products are transferred to the warehouse of fabricated products after passing a quality check control. There they are stored in cartons provided with markings enabling product identification. Products are stored according to the type. The product name and number of items are also placed on the carton. Depending on the agreement with a client, half masks are packed into foil bags – 1, 3 or 5 items per bag, respectively and then packed into cartons. Product is sent to the client by a shipping company.

Procedure for complaints

Inspectors learnt about the mode of procedure adopted in case of any complaints about the major product. Manufacturer has prepared a register of complaints including a date the complaint was accepted, subject of complaint, the mode of solving a problem, and a person in charge. Complaints are accepted in a written form, by letter or e-mail. Manufacturer has prepared a Complaint Form including

- place and date,
- client's data,

- subject of complaint (including a date the product was purchased, receipt or invoice number),
- submission of the complaint (description of defects and circumstances of their development, when defects were found),
- remedial measures/demands lodged by the complaining party,
- place for legible signature of the representative of the complaining party.

The form also includes space for the manufacturer's annotations (decision about the complaint, statement on the complaint, statement on the legitimacy or rejection of complaint along with relevant reasons), a date when complaint arrived, details about a person considering the complaint, a date the complaint was considered, a mode of further procedure for complaint, date and signature of the person considering the complaint. There were no complaints submitted when Contract UE-5-2018-C2 of 18 December 2018 was effective.

Collection of the samples for testing

The samples of half masks 7020 GD FFP2 NR D (14 items) and 7021 GDV FFP2 NR D (4 items) were collected at random from the warehouse of fabricated products. The collection of samples was documented in the sample collection note dated as of 25 September 2019.

12. Results of sample testing performed during the control check:

Product	Parameter tested
7020 GD FFP2 NR D	EN 149:2001+A1:2009 p. 7.16 Breathing resistance

Results of testing

As received	Flow rate	1					2					3					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
Inhalation	30 l/min	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3
	95 l/min	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3
Exhalation	160 l/min	2,4	2,3	2,3	2,3	2,4	2,3	2,3	2,3	2,4	2,3	2,3	2,4	2,3	2,4	2,3	2,3

Simulated wearing treatment	Flow rate	4					5					6					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
Inhalation	30 l/min	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3
	95 l/min	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3
Exhalation	160 l/min	2,3	2,3	2,3	2,4	2,3	2,4	2,3	2,3	2,4	2,3	2,4	2,3	2,4	2,3	2,3	2,3

Temperature conditioned	Flow rate	7					8					9					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
Inhalation	30 l/min	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3
	95 l/min	1,3	1,2	1,2	1,2	1,3	1,2	1,2	1,3	1,2	1,2	1,3	1,2	1,2	1,3	1,2	1,3
Exhalation	160 l/min	2,3	2,3	2,4	2,4	2,3	2,3	2,4	2,3	2,3	2,3	2,4	2,4	2,3	2,4	2,3	2,3

Flow conditioned	Flow rate	10					11					12					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
Inhalation	30 l/min	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3
	95 l/min	1,2	1,3	1,3	1,2	1,2	1,2	1,2	1,3	1,3	1,3	1,2	1,2	1,2	1,2	1,2	1,3
Exhalation	160 l/min	2,3	2,3	2,3	2,4	2,3	2,3	2,3	2,3	2,3	2,3	2,4	2,4	2,4	2,3	2,4	2,4

A: facing directly ahead, B: facing vertically upwards, C: facing vertically downwards, D: lying on the left side, E: lying on the right side

Assessment of conformity with standard

Classification	Maximum permitted resistance (mbar)					
	Inhalation			Exhalation		
	30 l/min	95 l/min	160 l/min	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0	0.6	2.1	3.0
FFP2	0.7	2.4	3.0	0.7	2.4	3.0
FFP3	1.0	3.0	3.0	1.0	3.0	3.0

Assessment of conformity with certificate provisions

Conformity confirmed



Product	Parameter tested	Results of testing		Assessment of conformity with standard	Assessment of conformity with certificate provisions
		A.R.			
7021 GDV FFP2 NR D	EN 149:2001+A1:2009 p. 7.12 Carbon dioxide content of the inhalation air	A.R.	0,51 %	≤ 1,0 %	Conformity confirmed
		A.R.	0,49 %	Mean value	
		A.R.	0,50 %		

13. Laboratory testing report

Testing reports:

- No 2019-W-142 dated as of 19 December 2019,
- No 2019-W-143 dated as of 19 December 2019.

Tests were done by National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing) TESTING CNAS L1499, No.55 Taoranting Street, Xicheng District, Beijing, China.

ASSESSMENT AND FINAL CONCLUSION

Assessment of the results of laboratory tests of the product samples collected on the day of inspection (25 September 2019) confirmed conformity of protective parameters with the requirements specified in the relevant harmonized standard and the type stipulated in the certificates from the EU-type examination No ITT.43.56.6.3.244.PPE.2534 Issue II of 01 October 2019 and applicable requirements stipulated in Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

OBSERVATION 1/1: Automax Industrial Ltd. has no clear-cut rules or regulations on the frequency of metrological control of the applied measurement devices.

Observation should be analyzed and – if needed – relevant measurements should be undertaken to eliminate any real or hypothetical irregularities prior to the successive control in the following year. Within 2 months since the receipt of the inspection report Automax Industrial Ltd is obligated to notify ITT CERTEX Sp. z o.o. of the planned measures with reference to the aforementioned observation.

The inspection findings proved that the process of production the goods stipulated in item no 2 of the herein report and its monitoring at Automax Industrial Ltd is homogenous as regards the products under the herein certificates.

Michał Górski
President of Board

Łódź, 20 December 2019

Note

1. Copying of the report otherwise than in full requires a written consent of the Head of Certification Department.
2. Total number of report pages: 5.