



# BM-026

## EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of BALTIC MASKS.

Regulations that the following product meets:

**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**

**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC**

We hereby declare that the following product specified meet the provision of the regulations indicated above. This declaration is supported by the Quality System approval to ISO 9001 issued by SERTIKA.

All supporting documentation is retained at the premises of the manufacturer.

<b>MANUFACTURER:</b>	<b>BALTIC MASKS, UAB Savanoriu ave. 178F, Vilnius, Lithuania</b>
<b>SRN (Single Resistance Number):</b>	<b>LT-MF-000008992</b>
<b>PRODUCT:</b>	<b>MEDICAL PARTICLE FILTERING HALF MASK (DISPOSABLE, NON-STERILE)</b>
<b>MEDICAL DEVICE BRAND NAME:</b>	<b>BALTIC MASKS</b>
<b>MODEL:</b>	<b>BM-026</b>
<b>Basic UDI-DI:</b>	<b>477902083BM02679</b>

### QUALITY ASSURANCE AND CONFORMITY

REGULATION:	PPE Regulation (EU) 2016/425	MD Regulation (EU) 2017/745
CONFORMITY ASSESSMENT PROCEDURE:	Annex V and Annex VII	Article 19, Annex II and Annex III
STANDARD:	EN149:2001+A1:2009	EN 14683:2019+AC:2019
CLASSIFICATION ACCORDING TO REGULATION:	CATEGORY III according to Annex I	CLASS I according to Rule 1 of Annex VIII
CLASSIFICATION ACCORDING TO STANDARD:	FFP2 NR D	TYPE IIR
NOTIFIED BODY	Polski Rejestr Statków S.A. Notified Body No. 1463	N/A
CERTIFICATE NUMBER:	CW/PPER/19/07/2021 (Module B) CW/PPER/1/09/2021 (Module C2)	N/A
TEST REPORT NUMBER:	2021250637-R1 CL/PCLB8/1/9/2021	AR-22-YL-000145-02

This declaration applies to all specimens manufactured identical to the model submitted for evaluation. Assessment of compliance of the product with the requirements relating to safety standards and legal requirements listed above was performed by manufacturer. Other relevant legal requirements for product and manufacturing must be observed.



VILNUS, LITHUANIA, DATE 2022 01 12  
General Manager Jelizaveta Shukiene

This declaration is the responsibility of the Manufacturer

Document valid until 2022 09 02



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Annex**

MODEL	PACKAGING	COLOR	UDI-DI
BM-026	POLYBAG, 10 PCS	WHITE	4779020832163
BM-026	POLYBAG, 2 PCS	WHITE	4779020832224