

EU Declaration of Conformity

BALTIC MASKS declares that this medical device complies with the following regulations:

MANUFACTURER:	BALTIC MASKS, UAB Savanoriu ave. 178F, Vilnius, Lithuania
BASIC UDI-DI:	477902083BM22077
SRN (SINGLE RESISTANCE NUMBER):	LT-MF-000008992
MEDICAL DEVICE:	MEDICAL DISPOSABLE NON-STERILE FACE MASK
MEDICAL DEVICE BRAND NAME:	BALTIC MASKS
MODEL:	BM-220
REGISTRATION NUMBER:	LT-CA01/MDD/1-00064/21
CLASSIFICATION:	CLASS I according to Rule 1 of Annex VIII MDR (EU) 2017/745
PRODUCT DESCRIPTION:	Medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. This intended purpose is normally to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier should also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. Single use only.

QUALITY ASSURANCE AND CONFORMITY:

Regulation: **Medical Device Regulation (EU) 2017/745**
Conformity assessment procedure: **Article 19 Annex II and Annex III according to Regulation (EU) 2017/745**
Standard: **EN 14683:2019+AC:2019**
Type: **IIR**

This declaration of conformity is issued under the sole responsibility of BALTIC MASKS. This is hereby declared that following designated medical device complied with the essential requirements of above Regulation(s) and standards.
All supporting documentation is retained at the premises of the manufacturer.



VILNUS, LITHUANIA, DATE 2022 04 06
Quality Manager Evgenij Shkulepa

Document valid until 2023 04 06

Page 1 of 2

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Annex**

MODEL	PACKAGING	COLOR	UDI-DI
BM-220	CARTON BOX, 50 PCS	LIGHT BLUE	4779020831234
BM-220	CARTON BOX, 50 PCS	BLACK	4779020832071
BM-220	CARTON BOX, 40 PCS	BLACK	4779020832088
BM-220	POLYBAG, 10 PCS	LIGHT BLUE	4779020831296
BM-220	CARTON BOX, 10 PCS	BLACK	4779020832064
BM-220	POLYBAG, 10 PCS	BLACK	4779020832286
BM-220	POLYBAG, 2 PCS	LIGHT BLUE	4779020832453
BM-220	POLYBAG, 2 PCS	BLACK	4779020832446