BALTIC MASKS

BM-220

EU Declaration of Conformity

INSPE declares that this medical device complies with the following regulations:

MANUFACTURER:	InSpe IĮ Savanoriu ave. 178F, Vilnius, Lithuania
Basic UDI-DI	**4779020831234**
SRN (Single Resistance Number)	**LT-MF-000004390**
MEDICAL DEVICE:	**MEDICAL DISPOSABLE NON STERILE FACE MASK**
MEDICAL DEVICE BRAND NAME:	**BALTIC MASKS**
MODEL:	**BM-220**
CLASSIFICATION:	**CLASS I according 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 InSpe. 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

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LIETUVOS RESPUBLIKA * REPUBLIC OF LITHUANIA * VILNIUS *
InSpe, IĮ
Personal enterprise

VILNUS, LITHUANIA, DATE 2021 05 17
General Manager Guy Shapira

Document valid until 2022 05 17.

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