

## EU Declaration of Conformity

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

<b>MANUFACTURER:</b>	InSpe II Savanoriu ave. 178F, Vilnius, Lithuania
<b>MEDICAL DEVICE:</b>	<b>MEDICAL DISPOSABLE NON STERILE FACE MASK</b>
<b>MEDICAL DEVICE BRAND NAME:</b>	<b>BALTIC MASKS</b>
<b>MODEL:</b>	<b>BM-220</b>
<b>CLASSIFICATION:</b>	<b>CLASS I according Rule 1 of Annex IX of MDD 93/42/EEC</b>
<b>PRODUCT DESCRIPTION:</b>	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:

Directive:	<b>Medical Device Directive 93/42/EE</b>
Conformity assessment procedure:	<b>Annex VII of MDD 93/42/EEC</b>
Standard:	<b>EN 14683:2019+AC:2019</b>
Type:	<b>IIR</b>

This is hereby declared that following designated medical device complied with the essential requirements of above Council Directive(s) and standards.



VILNUS, LITHUANIA, DATE 2021 02 25  
General Manager Guy Shapira



Document valid until 2021 08 26.