BALTIC MASKS

BM-920

EU Declaration of Conformity

Changzhou Shuangma Medical Devices Co. declares that this medical device complies with the following regulations:

MANUFACTURER:	**Changzhou Shuangma Medical Devices Co., Ltd.** San He Kou Development Zone, Zhenglu, Tianning, Changzhou, 213115, Jiangsu, China
MEDICAL DEVICE:	**MEDICAL DISPOSABLE NON STERILE FACE MASK**
MEDICAL DEVICE BRAND NAME:	**BALTIC MASKS**
MODEL:	**BM-920**
CLASSIFICATION:	**CLASS I**
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.

QUALITY ASSURANCE AND CONFORMITY:

Directive:	**Medical Device Directive 93/42/EEC**
Standard:	**EN 14683:2019+AC:2019**
Type:	**IIR**
Test report:	**60425394 001 (TUV dated 2020.11.27)**

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

CE

VILNUS, LITHUANIA, DATE 2020 11 27
InSpe (BALTICMASKS Brand holder) CEO,
Guy Shapira

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

Changzhou, 2020-11-27

Changzhou, 2020-11-27

Xu Aiping, General Manager

Xu Aiping

Document valid until 2021 11 27

This declaration is the responsibility of the Manufacturer

InSpe, II Address: Savanoriu 178F, 03154 Vilnius, Lithuania registration nr.: 120650387. VAT: LT206503811
Bank: Swedbank AB Bank code: 73000 SWIFT: HABALT22 Account: LT93 7300 0100 8585 7835