

## EU Declaration of Conformity

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

<b>MANUFACTURER:</b>	<b>Changzhou Shuangma Medical Devices Co., Ltd.</b> San He Kou Development Zone, Zhenglu, Tianning, Changzhou, 213115, Jiangsu, China
<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-920</b>
<b>CLASSIFICATION:</b>	<b>CLASS I</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.
<b>QUALITY ASSURANCE AND CONFORMITY:</b>	
Directive:	<b>Medical Device Directive 93/42/EEC</b>
Standard:	<b>EN 14683:2019+AC:2019</b>
Type:	<b>IIR</b>
Test report:	<b>SL52035285591101TX (SGS August 24, 2020)</b>

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



Changzhou, 2020-11-10

Xu Aiping, General Manager

Document valid until 2021 11 10