BALTIC MASKS

BM-220

EU Declaration of Conformity

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

MANUFACTURER:	**Hubei Qianjiang Kingphar Medical Material Co., Ltd.** **Yuanguang Road, 433100, Qianjiang, P. R. China**
MEDICAL DEVICE:	**MEDICAL DISPOSABLE NON STERILE FACE MASK**
MEDICAL DEVICE BRAND NAME:	**Non Woven Surgical Mask**
MODEL:	**BM-220**
CLASSIFICATION:	**CLASS II**
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:	**Test Report No.: 721653406** **Report Date: 14 April 2020**

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

CE

Nordeko SAFETY, DATE 2020 08 26
General Manager Simon Maak

Document valid until 2022 08 26.