

Doc. No.	KSX/TD-MMM-017	Title	EC Declaration of Conformity of Nonwoven Face Mask		
Ver./Rev.No.	A/0	Issued Date	2020.02.28	Page/Total	1 / 1

EC Declaration of Conformity

Manufacturer Name: Kingstar Medical (Xianning) Co., Ltd.

Manufacturer Address: No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, the People's Republic of China.

Location of Manufacturer: Xianning City, Hubei Province, China.

Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)

Address of their Registered Place of Business: Eiffestrasse 80, D-20537, Hamburg, Germany

Location be established: Germany

Name of the device: Nonwoven Face Mask

Size of the device: 17.5cm x 9.5cm

UMDNS Code: 12477, Mask

Standard applied: EN 14683: 2019 + AC: 2019 E, Type II

Risk Class of the Device: Class I, based on Annex IX of MDD 93/42/EC

The conformity assessment procedure performed: Annex VII of MDD 93/42/EC

Declaration: This declaration of conformity is issued under the sole responsibility of Kingstar Medical (Xianning) Co., Ltd. We hereby declare that the medical device specified above meet the provision of the EC Council Directives (MDD 93/42/EEC). This declaration is supported by the quality system approval to ISO 13485 by TÜV SÜD Product Service GmbH

All supporting documentation is retained at the premises of the manufacturer.

Signed for and on behalf of:

Place of Issue: Xianning City, Hubei Province, China.

Date of Issue: 2020-03-14

Print Name: Yuanqiang Ren

Function: Management Representative

Signature: *Yuanqiang Ren 2020.3.14*