

Doc. No.	KSX/TD-NFM-017	Title	EU Declaration of Conformity of Nonsterile Non-woven Face Mask		
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EU 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

Basic UDI-DI: 6971872201311000LT

Registered Trade Name / Mark: Kingstar / HARTMANN

Name of the device: Nonsterile Non-woven Face Mask

CND Code: T0206, Surgical Face Masks

UMDNS Code: 12447, Masks

Intended Purpose: Nonsterile Non-woven Face Mask is intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment.

Risk Class of the Device: Class I, based on Rule 1 of Annex VIII of the Regulation (EU) 2017/745

All non-invasive devices are classified as class I.

The conformity assessment procedure performed: According to Article 19 of the Regulation (EU) 2017/745, draw up this EU declaration of conformity which contain the information set out in Annex IV of the Regulation (EU) 2017/745.

CS used or Standard applied: EN 14683: 2019 + AC: 2019(E)

Identification of the device: Please find in Annex I.

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 Regulation (EU) 2017/745 for medical device. 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.

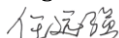
Signed for and on behalf of:

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

Date of Issue: 2021.06.25

Print Name: Yuanqiang Ren

Function: Management Representative

Signature: 

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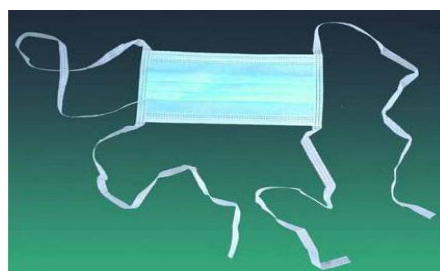
Annex I --- Identification of the Device Covered by the EU Declaration of Conformity

1. Identification of the Device

Table --- Identification of the Device

No.	Specification	Type	Packaging Configuration	
			pcs /paper box	boxes/case
9920700	17.5cm x 9.5cm, 3-ply, Tie-on, Blue	Type II	50	40
9920710	17.5cm x 9.5cm, 3-ply, Tie-on, Green	Type II	50	40

2 Photograph of Nonsterile Non-woven Face Mask



Tie-on Non-woven Face Mask

3 Revise History

No.	Date	Version	Content Modification	Person
1	2021.05.12	A/0	Initial release	Jiansen Yin
2	2021.06.25	A/1	Update the information of Registered Trade Name/ Mark	Jiansen Yin