

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.

**SRN of the Manufacturer:** Not available yet.

**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

**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), Type II

**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: 2020.08.29

Print Name: Yuanqiang Ren

Function: Management Representative

Signature: 任远强

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

### 17. Identification of the Device

Table --- Identification of the Device

No.	WERO REF	Kingstar Article Number	Specification	Type	Packaging Configuration
1	3703	5888110040	Non-woven face masks, 17.5cm x 9.5cm, 3-ply, Ear loops, Blue	Type II	50 pcs/paper box, 40boxes/case

### 2 Photograph of Nonsterile Non-woven Face Mask



Photo 1 --- Ear Loops Non-woven Face Mask

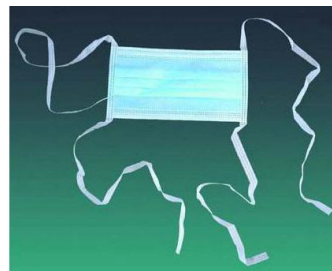


Photo 2 --- Tie-on Non-woven Face Mask

### 3 Revise History

No.	Date	Version	Content Modification	Person
1	2020.02.28	A/0	Initial release	Jiansen Yin
2	2020.08.29	A/1	Update the format of page 1	Jiansen Yin