

Doc. No.	KSW/TD-EGVN-017	Title	EU Declaration of Conformity of NonSterile Examination Gloves		
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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:** Eifflstrasse 80, D-20537, Hamburg, Germany

**Location be established:** Germany

**Basic UDI-DI code:** 6973554891381000XU

**Registered Trade Name / Mark:** Kingstar

**Name of the device:** Nonsterile Examination Gloves

**CND Code:** T01020201, EXAMINATION / TREATMENT GLOVES

**UMDNS Code:** 11882, Gloves, Examination/Treatment

**Intended Purpose:** Intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanitary or medical purposes. The device is used mainly as a two-way barrier to protect patient/staff against contaminants.

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

**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 455-1:2020 and EN 455-4: 2009

**Identification of the device:** Please find in Annex I

**Declaration:** This declaration of conformity is issued under the sole responsibility 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: 

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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.	WERO REF	Kingstar Article Number	Specification	Packaging Configuration
1	230356	5142410010	L / Nitrile/ 4±0.2g /pc	4 pcs/PE bag, 250 bags/case
2	230358	5142410020	XL / Nitrile/4±0.2g /pc	4 pcs/PE bag, 250 bags/case

### 2 Photograph of Nonsterile Nitrile Glove



Photo 1 --- Nonsterile Nitrile Gloves in PE bag



Photo 2 --- Nitrile Gloves