

Doc. No.	KSX/TD-APN-017-100	Title	EU Declaration of Conformity of Alcohol Pads		
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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

SRN of the manufacturer: CN-MF-000006015

Registered Trade Name / Mark: Kingstar

Name of the device: Alcohol Pads

CND Code: M020299, non-woven gauzes - others

UMDNS Code: 15252, Sponges, Other

Basic UDI-DI: 6971872201401000LV

Intended Purpose: The Alcohol Pads are intended for skin cleaning prior to subcutaneous injections and the taking of capillary blood samples.

Risk Class of the Device: Class I, based on Rule 1 of Annex VIII of the 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: N/A

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. 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: 2022.07.01

Print Name: Fan Rong

Function: Management Representative

Signature: 

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Annex I --- Identification of the Device Covered by the EU Declaration of Conformity**Identification of the Device****Table --- Identification of the Device, Alcohol Pads**

No.	Customer Art. No.	Specification	Packaging Configuration
1	4110020	Alcohol Pads 60x30mm P100x1	1 pc/pouch, 100 pouches/folding box, 70 boxes/carton