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.
SRN of the Manufacturer: CN-MF-000006015
Location of Manufacturer: Xianning City, Hubei Province, China.
Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
SRN of the Authorized Representative: DE-AR-000000001
Address of their Registered Place of Business: Eiffestrasse 80, D-20537, Hamburg, Germany
Location be established: Germany

Basic UDI-DI: 6971872201401000LV
Registered Trade Name / Mark: Kingstar
Name of the device: Alcohol Pads
EMDN Code: M020299, Non-Woven Gauzes - Others
UMDNS Code: 15252, Sponges, Other
GMDN Code: 61694, Skin-cleaning wipe, non-sterile

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: Please find in Annex 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. 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.

Notified Body: TÜV SÜD Product Service GmbH
Address: Ridlerstr. 65, 80339 Munich, Germany
Identification No.: CE0123

Signed for and on behalf of:
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2023.03.30
Print Name: Fan Rong
Function: Management Representative
Signature:

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

1 Identification of the Device

Table --- Identification of the Device, Alcohol Pads

No.	Customer Art. No.	Specification	Packaging Configuration
1	4110020	Alcohol Pads 60x30mm, non-woven fabric	1 pc/pouch, 100 pouches/ box, 70 boxes/carton

2 Photograph of Alcohol Pad

Photo 1 --- Alcohol Pad in packaging

Photo 2 --- Alcohol Pad

Annex II --- European Harmonization and International Standard list

No.	Reference and title of the standard (and reference document)	First publication OJ
1	EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1: 2016, Corrected version 2017-03)	This is the first publication
2	EN 1041:2008+A1:2013Information supplied by the manufacturer of medical devices	25.9.2013
3	EN ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	2018-08
4	EN ISO 10993-1: 2018/AC: 2010	18.1.2011
5	ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1	08.2018
6	EN ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	01.06.2009
7	EN ISO 10993-10: 2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	21.8.2013
8	EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices (ISO 14971: 2007, corrected version 2007-10-01)	30.8.2012
9	EN ISO 14971: 2019 Medical devices - Application of risk management	18.12.2019
10	EN 62366-1: 2015 Medical devices – Part 1: Application of usability engineering to medical devices	30.06.2015
11	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	First publication
12	EN ISO 13485:2016/AC:2018	28.03.2018
13	MEDDEV 2.7/1 Revision 4, Clinical evaluation, a Guide for manufacturers and notified bodies, under directives 93/42/EEC and 90/385/EEC	01.7.2016