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|--------------|--------------------|-------------|--------------------------------------------------------|------------|-------|
| Doc. No.     | KSX/TD-CBN-017-183 | Title       | EU Declaration of Conformity of Nonsterile Cotton Buds |            |       |
| Ver./Rev.No. | A/1                | Issued Date | 2021.11.05                                             | Page/Total | 1 / 2 |

## 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:** Nonsterile Cotton Buds

**CND Code:** V9013, SAMPLES COLLECTION, SWABS

**UMDNS Code:** 15066, Swabs, Cotton

**Basic UDI-DI:** 6971872201131000LP

### Intended Purpose:

- Sanitary purpose: cleaning ears, making up, taking care of pets etc.
- Medical purpose:
  - Disinfecting body injection site or minor superficial wound after dipping disinfectant (Iodine etc.);
  - Cleaning the exudate near wound, only contacting intact skin;
  - Cleaning and/or aid to medical examination via invading body natural orifices such as oral, nasal and/or ear cavities. (Invasive device)

**Risk Class of the Device:** Class I, based on Rule 5 of Annex VIII of the Regulation (EU) 2017/745.

*All invasive devices with respect to body orifices, other than surgically invasive devices, — class I if they are intended for transit use;*

**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:** European Pharmacopoeia <Cotton, Absorbent>

**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: 2021.11.05

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

#### Identification of the Device

**Table --- Identification of the Device**

| No. | Catalogue Number | Specification                             | Packaging Configuration                                |
|-----|------------------|-------------------------------------------|--------------------------------------------------------|
| 1   | 1260             | 150x2.2x4.7mm, single head, wooden stick  | 100pcs/valve bag, 10bags/box, 20boxes/case             |
| 2   | 1261             | 150x2.5x7.9mm, single head, wooden stick  | 100pcs/valve bag, 10bags/box, 10boxes /case            |
| 3   | 1263             | 150x2.5x10.5mm, single head, wooden stick | 50pcs/valve bag, 10bags/box, 10boxes /case             |
| 4   | 1268             | 150x4x10.5mm, single head, plastic stick  | 50pcs/valve bag, 10bags/box, 10boxes /case             |
| 5   | 4046             | 75x2.2x4.5mm, double head, plastic stick  | 200pcs/plastic box, 10plastic boxes/box, 10boxes /case |
| 6   | HOG04768761      | 150x2.2x4.7mm, single head, wooden stick  | 100pcs/valve bag, 10bags/case                          |

#### Photograph of the Devices

