

Doc. No.	KSX/TD-CBS-015	Title	Declaration of Conformity of Sterile Cotton Bud		
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Declaration of Conformity
(Sterile Cotton Bud)

Manufacturer:

Name: Kingstar Medical (Xianning) Co., Ltd.

Address: No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, the People's Republic of China

EU representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, D-20537, Hamburg, Germany

Product Name: Sterile Cotton Bud

Intended use: intended for cleaning or applying a substance (e.g., medication) to a superficial wound or body orifice, absorbing little exudates, and/or to take specimens from a patient.

Classification (MDD, Annex IX): MDD 93/42/EC, Annex IX

Product Name	Rule	Class
Sterile Cotton Bud	Rule: 4	Is
	Rule: 5	Is

UMDNS code: 15066, Swabs, Cotton

Conformity Assessment Route: Annex V

Identification of the Device:

50mm to 200mm (stick length) x 1mm to 5mm (stick diameter) x 3mm to 15mm (cotton diameter)

Declaration: We hereby declare that the manufacturer is exclusively responsible for the declaration of conformity, the above mentioned products meet the provisions of the following EC Council Directives (MDD 93/42/EEC) and the relevant harmonised standards used. All supporting documentations are retained under the premises of the manufacturer and the Authorised Representative. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

- **Medical Device Directive:** COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
- **Relevant Harmonised Standards Used:** European Pharmacopoeia <Cotton, Absorbent>

Notified Body Name: TÜV SÜD Product Service GmbH

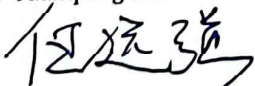
Address: Ridlerstr. 65, 80339 Munich, Germany

Identification No.: CE0123

EC-Certificate No.: G2S 097364 0012 Rev.00

Certificate expired date: 2024-05-26

Print Name: Yuanqiang Ren

Signature: 

Position: Management Representative

Date: 2021.03.12