

Doc. No.	KSX/TD-GBS-015	Title	Declaration of Conformity of Sterile Gauze Balls		
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**EC Declaration of Conformity**  
(Sterile Gauze Balls)

**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 Gauze Balls

Intended use: intended for absorption of body fluids, to cover wounds, and as carrier for the application of disinfectants and cleaning solutions.

List of CE-labeled Products: 2cm to 60cm (width) x 2cm to 60cm (length)

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

Product Name	Rule	Class
Sterile Gauze Balls	Rule: 4	Is
	Rule: 5	

Conformity Assessment Route: Annex V

**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 EC 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:** EN 14079: 2003

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

Signature:



Position: Management Representative

Date: 2021.03.13