

Doc. No.	KSX/TD-GRX-015-183	Title	EC Declaration of Conformity of Sterile/Nonsterile X-Ray Detectable Gauze Rolls		
Ver./Rev.No.	B/0	Issued Date	2020.12.02	Page/Total	1 / 2

EC Declaration of Conformity
(Sterile/Nonsterile X-Ray Detectable Gauze Rolls)

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/Nonsterile X-Ray Detectable Gauze Rolls

List of CE-labeled Products: See Appendix 1

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

Product Name	Rule	Class
Sterile/Nonsterile X-Ray Detectable Gauze Rolls	Rule: 6	IIa

UMDNS code: 13705 (Sponges, X-ray Detectable)

Conformity Assessment Route: Annex V + Annex VII

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).


Notified Body Name: TÜV SÜD Product Service GmbH,

Address: Ridlerstr. 65, 80339 Munich, Germany

Identification No.: CE0123

EC-Certificate No.: G2 097364 0008 Rev. 02

Certificate expired date: 2024-05-26

Signature: 

Position: Management Representative

Date: 2020.12.02

Doc. No.	KSX/TD-GRX-015-183	Title	EC Declaration of Conformity of Sterile/Nonsterile X-Ray Detectable Gauze Rolls		
Ver./Rev.No.	B/0	Issued Date	2020.12.02	Page/Total	2 / 2

Appendix 1 --- List of CE-labeled Products

Classification	Meditrade Code	Meditrade Name	Kingstar name	Kingstar REF
Ila	1446	ABE Tamponadebinde RK unsteril	Nonsterile X-ray detectable Gauze rolls	C006000X
Ila	4312	ABE Tamponadebinde RK steril	Sterile X-ray detectable Gauze rolls	C106001X