

Doc. No.	KSX/TD-NSS-015-183	Title	EC Declaration of Conformity of Sterile Nonwoven Sponges		
Ver./Rev.No.	B/0	Issued Date	2021.03.13	Page/Total	1 / 2

EC Declaration of Conformity
(Sterile Nonwoven Sponges)

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 Nonwoven Sponges

List of CE-labeled Products: See Appendix 1

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

Product Name	Rule	Class
Sterile Nonwoven Sponges	Rule: 4	Is

UMDNS code: 13703 (Sponges, Rayon Cellulose)

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.: G2S 097364 0012 Rev.00

Certificate expired date: 2024-05-26

Signature: 

Position: Management Representative

Date: 2021.03.13

Doc. No.	KSX/TD-NSS-015-183	Title	EC Declaration of Conformity of Sterile Nonwoven Sponges		
Ver./Rev.No.	B/0	Issued Date	2021.03.13	Page/Total	2 / 2

Appendix 1 --- List of CE-labeled Products

Classification	Meditrade Code	Meditrade Name	Kingstar name	Kingstar REF
Is	1137	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109065
Is	1138	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109068
Is	1139	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109072
Is	1140	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109076
Is	1219	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109092
Is	1800	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109067
Is	1801	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109070
Is	1802	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109074
Is	1803	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109077
Is	4225	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109080
Is	4226	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109085
Is	4227	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109089
Is	4376	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109083
Is	4377	BeeSanaVlieskompressesteril	Sterile non-woven sponges	C109087
Is	1232	BeeSanaVliesschlitzkompressesteril	Sterile non-woven sponges	C109066
Is	1233	BeeSanaVliesschlitzkompressesteril	Sterile non-woven sponges	C109073
Is	1234	BeeSanaVliesschlitzkompressesteril	Sterile non-woven sponges	C109069
Is	4105	BeeSanaVliesschlitzkompressesteril	Sterile non-woven sponges	C109075