EU Declaration of Conformity

Gauze Products (Class Is)

This Declaration of Conformity is issued under the sole responsibility of Winner Medical Co., Ltd.

We hereby declare that the mentioned product/ attached list of products with CE marking comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745. And the CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Legal Manufacturer:	Winner Medical Co., Ltd. Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000005692
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001
Product Name:	Refer to Appendix A
EMDN Code and Term Description:	Refer to Appendix A
Basic UDI-DI:	Refer to Appendix A
Intended Purpose:	Refer to Appendix A
Risk Classification:	Class I Sterile as per Rule 4 in Annex VIII of EU Medical Device Regulation (EU) 2017/745
Conformity Assessment Route:	Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class I Devices in sterile condition)
Applicable Standards:	EN ISO 13485:2016/A11:2021 EN ISO 14971:2019/A11:2021 EN ISO 20417: 2021 EN ISO 15223-1: 2021 EN ISO 10993-1: 2020 EN ISO 11137-1:2015/A2:2019

	(applicable for Radiation Sterilization) EN ISO 11135:2014/A1:2019 (applicable for EO Sterilization) EN ISO 10993-7: 2008/A1: 2022 (applicable for EO Sterilization) EN ISO 17665-1:2006 (applicable for Steam Sterilization) EN ISO 11737-1:2018/A1:2021 EN ISO 11737-2:2020 EN 14079: 2003
References to any CS:	Not Applicable
Identification of Notified Body:	TÜV SÜD Product Service GmbH 0123 Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY
Identification of the Certificate(s):	EU Quality Management System Certificate (MDR) No. G11 046241 0074 Rev.02, issued by TÜV SÜD Valid from: 2024-10-18 Valid until: 2028-07-09
Identification of the person authorized to sign on behalf of Legal Manufacturer:	**Name:** Xiaomeng Yang **Signature:** Xiaomeng Yang Management Representative Place of Issue: Shenzhen, China Date: 2024-10-18

Appendix A: List of Product Range Covered under this Declaration of Conformity

General Device Group	Product	EMDN Code	Risk Classification	Basic UDI-DI
Gauze Products	Gauze Swabs/Sponges without X-ray Detectable Element	M0201020101 (COTTON GAUZES, FOLDED, NOT RX, STERILE)	Class I Sterile Rule 4	For EO Sterilization: 694109408333FF For R Sterilization: 694109408345FN For Steam Sterilization: 694109408341FE
	Gauze Lap Sponges without X-ray Detectable Element			
	Gauze Balls without X-ray Detectable Element			
	Gauze Rolls without X-ray Detectable Element			
	Gauze Trach Sponges without X-ray Detectable Element			

Intended purpose:

- Gauze Swabs/Sponges without X-ray Detectable Element are wound treatment device and primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. This is a single use device.
- Gauze Lap Sponges without X-ray Detectable Element are wound treatment device and primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. This is a single use device.
- Gauze Balls without X-ray Detectable Element are wound treatment device and primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. This is a single use device.
- Gauze Rolls without X-ray Detectable Element are wound treatment device and primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. This is a single use device.
- Gauze Trach Sponges without X-ray detectable element has special shape intended to be used in tracheotomy nursing process for absorbing exudates and skin, wound care. This is a single use device.

Effective

Revision History

Rev No.	Date	Comment	Author
A/0	2023-07-10	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Mingni Liu
A/1	2024-06-11	Update for the new certificate version	Jinling Luo
A/2	2024-07-29	Standards Update	Jinling Luo
A/3	2024-10-18	Update for the new certificate version	Jinling Luo

Effective

Statement to EC Declaration of Conformity (Doc No.: WN-CE(MDR) 102-13)

We,

Winner Medical Co., Ltd.
Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen, China.

Declare that,
The following Gauze Products are covered by the EU Declaration of Conformity (Doc No.: WN-CE(MDR) 102-13 EU DoC of sterile Gauze product A0) which we issued, and can be placed in the market as a medical device according to REGULATION (EU) 2017/745.

WINNER code	Bbraun REF	Description	EMDN Code
601-013263	9031103N	Askina Kompr st 5x5cm 8f 17fd P5x2	M0201020101
601-013265	9031111N	Askina Kompr st 7,5x7,5cm 8f 17fd P5x2	M0201020101
601-013267	9031120N	Askina Kompr st 10x10cm 8f 17fd P5x2	M0201020101
601-013269	9031138N	Askina Kompr st 10x20cm 8f 17fd P5x2	M0201020101
601-013271	9031200N	Askina Kompr st 5x5cm 8f 17fd P25x2	M0201020101
601-013273	9031219N	Askina Kompr st 7,5x7,5cm 8f 17fd P25x2	M0201020101
601-013275	9031227N	Askina Kompr st 10x10cm 8f 17fd P25x2	M0201020101
601-013277	9031235N	Askina Kompr st 10x20cm 8f 17fd P25x2	M0201020101

Intended purpose

Gauze Swabs/Sponges without X-ray Detectable Element are wound treatment device and primarily intended to be used as mechanical barrier, for compression or for absorption of exudates. This is a single use device.

Signature: Anna Luo

Date: June 13, 2024

Effective

Name and Position: Anna Luo / Regulatory Affairs Engineer

Winner Medical Co., Ltd.