EU Declaration of Conformity

Synthetic Non-woven Product without X-ray detectable element

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 EN ISO 14971: 2019 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 11607-1:2020 EN ISO 11737-1: 2018 EN ISO 11737-2:2020 EN 14079: 2003 EN 1644-1 :1997 EN-1644-2: 2000
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.01, issued by TÜV SÜD Valid from: 2024-06-11 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: 2024-06-11

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

General Device Group	Product	EMDN Code	Risk Classification	Basic UDI-DI
Synthetic Non-woven Products	Sterile Swabs/Sponges without X-ray detectable element	M0202010101 NON-WOVEN FOLDED GAUZES, WITHOUT X-RAY DETECTABLE THREAD, STERILE	Class I Sterile, Rule 4	For Steam sterilization products: 694109405476FH For EO sterilization products: 694109405483FE For Irradiation sterilization products:694109405484FG
	Sterile Lap Sponges without X-ray detectable element			
	Sterile Balls without X-ray detectable element			
	Sterile Rolls without X-ray detectable element			

Intended purpose:

- Synthetic Non-woven 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 non-invasive and single use device.
- Synthetic Non-woven 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 non-invasive and single use device.
- Synthetic Non-woven 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 non-invasive and single use device.
- Synthetic Non-woven 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 non-invasive and single use device.

Revision History

Rev No.	Date	Comment	Author
A/0	2024-06-11	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Jinling Luo

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Annex to EU Declaration of Conformity (No.: WN-CE(MDR) 104-10 A/0)

The following Product names and Article codes are covered by the EU-Declaration of Conformity (Doc No.: WN-CE(MDR) 104-10 A/0, certificate No. G11 046241 0074 Rev. 01).

General Device Group	Product	EMDN Code	Risk Classification	Basic UDI-DI
Synthetic Non-woven Products	Sterile Swabs/Sponges without X-ray detectable element	M0202010101 NON-WOVEN FOLDED GAUZES, WITHOUT X-RAY DETECTABLE THREAD, STERILE	Class I Sterile, Rule 4	694109405483FE

Beiersdorf Product name	Beiersdorf Product Code NART	Winner Product Code
HP SOC STE 7,5X7,5CM 10 PCS INT	48794-00000-49	601-024242
EPL SOC STE 7,5X7,5CM 10 PCS EN_FR	48794-00001-49	601-024243
EPL SOC STE 7,5X7,5CM 10 PCS EN	48794-00002-49	601-024244
HP SOC STE 7,5X7,5CM 10 PCS INT	48794-00003-49	601-024245
HP SOC STE 7,5X7,5CM 10 PCS DE_FR_NL	48794-00004-49	601-027141
HP SOC STE 7,5X7,5CM 10 PCS ID	48794-00005-49	601-027143

Date: 2024.6.21

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Quality Management Department

Winner Medical Co., Ltd.