EC Declaration of Conformity
Regarding Medical Device Regulation(EU)2017/745

Manufacturer

Company: Jiangsu Guangyi Medical Dressing Co., Ltd.

Address:No.6 Jianzhong Road Xinpu Economic Development Zone Haizhou District Lianyungang 222344 Jiangsu P.R. China

SRN: CN-MF-000009827

European Representative

Company: SUNGO Europe B.V.

Address:Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR000000247

Product

Name: Wound Dressings

Model	Basic UDI-DI
PU with absorbent pad	697469268300008S
PU type	697469268300018U
Non-woven fabrics with absorbent pad	697469268300028W
Non-woven type	697469268300038Y
Absorbent pad	697469268300492

Classification: Class I sterile

Rule: Rule 4 indent 1, Annex VIII, Medical Device Regulation (EU)2017/745

Conformity assessment procedure: Chapters I of Annex IX Section 2 and 3 and Chapter III

Notified body:

TÜV Rheinland LGA Products GmbH

Tillystraße 2 90431 Nürnberg Deutschland

Notified Body no.: CE 0197

EC certificate no.:HZ 2011845-1

Issue date:2024-04-25

Valid until:2029-04-24

Manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of MDR Regulation(EU)2017/745, and its transposition into national laws. The products comply with the General Safety and Performance Requirements of Annex I, further applicable standards/common specifications and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

No.	Serial Number	Title and Description
Regulations		
1	MDR2017/745/EU	Medical Device Regulations
2	MEDDEV 2 12-1 Rev:8	Vigilance report form for field safety corrective action report Form Manufacturer's Field Safety Corrective Action Report
3	MEDDEV. 2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies
Standards		

4	EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
5	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
6	EN ISO 15223-1:2021	Symbols for use in the labelling of medical devices
7	EN 13726-2023	Test methods for wound dressings - Aspects of absorption, moisture vapour transmission, waterproofness and extensibility
8	BS ISO20417-2021	Medical devices-Information to be supplied by the manufacturer
9	EN ISO 10993-1:2020	Biological evaluation of medical devices---part 1: Evaluation and testing
10	EN ISO 10993-5:2016	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
11	EN ISO 10993-7:2008 /AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
12	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
13	ISO 10993-11:2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
14	EN ISO 10993-12:2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
15	EN ISO 11135:2014	Sterilization of health care products -Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
16	EN ISO11607-1:2020	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
17	EN ISO11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
18	EN ISO 11737-1:2018	Sterilization of health care devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products
19	EN ISO 11737-2:2020	Sterilization of health care products-Microbiological methods. Part 2: Tests of sterility performed in the defintion ,validation and maintenance of a sterilization process
20	EN 62366-1:2015	Medical devices. Part 1: Application of usability engineering to medical devices
21	EN 556-1:2001	Sterilization of medical devices- Requirements for medical devices to be designated "STERILE-Part 1: Requirements for terminally sterilized medical devices
22	BS EN 556-2:2015	Sterilization of medical devices- Requirements for medical devices to be designated “STERILE” - Part 2: Requirements for aseptically processed medical devices
23	ASTM D4169	Package testing

The above referenced products will bear the CE mark as below.

CE 0197

We confirm our product meets the requirements of Medical Device Regulation (EU)2017/745 and relevant harmonized standards

Name and Signature:

Position: General Manager

Date and Place: Lianyungang 2024.4.26