File No.: GY/JS-GNS-05 Version: A/1

## 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: Gauze/Nonwoven Sponges

Model	Basic UDI-DI
Gauze type	697469268500009G
Non- woven type	697469268500019J

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		
Regu	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		
Stan	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		



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EN ISO 15223-1:2021   Symbols for use in the labelling of medical devices			File No.: G1/JS-GNS-03 V
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 devicespart 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 John School 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 Part 1: Requirements for materials, sterile barrier systems and packaging systems  16 EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems  17 EN ISO 11737-1:2018 Sterilization of health care devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products  18 EN ISO 11737-2:2020 Sterilization of health care products-Microbiological methods. Part 2: Tests of sterility performed in the definition 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. Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices.  22 BS EN 556-2:2015 Sterilization o	6	EN ISO 15223-1:2021	
BS ISO20417-2021   Medical devices-Information to be supplied by the manufacturer	7	EN 13726-2023	Test methods for wound dressings - Aspects of absorption,
Biological evaluation of medical devices part 1: Evaluation and testing			
testing Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals  EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization  Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization  Biological evaluation of medical devices Part 11: Tests for systemic toxicity  EN ISO 10993-11:2017 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials  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 Part 1: Requirements for medical devices  Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems  Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes  Sterilization of health care devices. Microbiological methods. Part 1: Determination of a population of microorganisms on products  Sterilization of health care products-Microbiological methods. Part 2: Tests of sterility performed in the definition ,validation and maintenance of a sterilization process  Description of medical devices requirements for medical devices of a sterilization of medical devices. Sterilization of medical devices Requirements for terminally sterilized medical devices. Requirements for terminally sterilized medical devices. Requirements for medical devices to be designated "STERILE-Part 1: Requirements for terminally sterilized medical devices. Requirements for medical devices to be designated "STERILE-Part 1: Requirements for aseptically processed medical devices. Part 2: Requirements for aseptically processed medical devices. Part 2: Requirements for aseptically processed medical devices. Part 2: Requirement	8	BS ISO20417-2021	
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11 EN ISO 10993-7:2008	10	EN ISO 10993-5:2016	Biological evaluation of medical devices - Part 5: Tests for in vitro
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Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	11	EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide
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viscose gauze			methods for Gauze/Nonwoven Sponge and absorbent cotton and
			viscose gauze



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



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

harmonized standards

Name and Signature:

Date and Place: Lianyungang 2024.4.26

Position:General Manager