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

## Manufacturer

Company: HEFEI C&P NONWOVEN PRODUCTS CO.,LTD

Address: NO.22 Park Road,Feidong New City Development Area,Hefei,Anhui,China
**SRN:CN-MF-000002304**

### European Representative

Company: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

**SRN:** NL-AR-000000247

## Product

Name: Reinforced Surgical Gown
Basic UDI-DI: 697527551REIGown002NH EMDN Code: T020402
Models: GR010,GR011,GR012,GR013,GR014

Classification: Class I sterile
Rule: Rule 1, Annex VIII, Medical Device Regulation (EU)2017/745

Conformity assessment procedure: Annex II+ Annex III+ Annex IX Chapter(I/III)
Notified body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431,Nürnberg, Germany

Notified Body no.: CE 0197

EC certificate no. :DZ 2081692-1

Issue date: 26th,April,2023

Valid until: 25th,April,2028

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.

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 the following harmonized standards.

| No. | Standard No. | Version | Title |
|---|---|---|---|
| 1 | Regulation(EU) 2017/745 | 2017 | Medical Device Regulation |
| 2 | EN ISO 14971 | 2019 | Medical Device -Application of Risk Management in Medical Device |
| 3 | EN ISO 15223-1 | 2021 | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements. |
| 4 | EN ISO 10993-1 | 2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| 5 | EN ISO 10993-5 | 2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) |
| 6 | EN ISO 10993-7 | 2008 | Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008) |
| 7 | EN ISO 10993-10 | 2021 | Biological Evaluation of Medical Device –Part 10: Test for skin sensitization |
| 8 | ENISO 10993-23 | 2021 | Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021) |
| 9 | EN ISO 20417 | 2021 | Medical devices — Information to be supplied by the manufacturer |
| 10 | EN ISO13485 | 2016 | Quality system—Medical devices-Particular requirements |
| 11 | EN 13795-1 | 2019 | Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns |
| 12 | EN 13795-2 | 2004/A1:2009 | Surgical Drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 2: Test methods |
| 13 | EN 13795-3 | 2006/A1:2009 | Surgical Drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 3: Performance requirements and performance levels |
| 14 | EN ISO 13938-1 | 1999 | Textiles - Bursting properties of fabrics - Part 1: Hydraulic method for determination of bursting strength and bursting distension |
| 15 | EN 29073-3 | 1992 | Textiles; test method for nonwovens; part 3: determination of tensile strength and elongation |
| 16 | EN ISO 811 | 2018 | Textiles - Determination of resistance to water penetration - Hydrostatic pressure test |
| 17 | EN ISO 22612 | 2005 | Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration |
| 18 | EN ISO 22610 | 2006 | Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration |
| 19 | EN ISO 9073-10 | 2004 | Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state |
| 20 | EN ISO 11135 | 2014 | Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine |

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| | | | control of a sterilization process for medical devices (ISO 11135:2014) |
| 21 | EN 1422 | 2014 | Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods |
| 22 | EN 556-1 | 2001/AC:2006 | Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices |
| 23 | EN 556-2 | 2015 | Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices |
| 24 | EN ISO 11737-2 | 2009 | Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process |
| 25 | ISO 11737-1 | 2018 | Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products |
| 26 | EN ISO 11607-1 | 2020 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) |
| 27 | EN ISO 11607-2 | 2020 | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) |
| 28 | ASTM-D4169-14 | | Standard Practice for Performance Testing of Shipping Containers and Systems |
| 29 | ASTM-D642-15 | | Test Method for Determining Compressive Resistance of Shipping Container, Components, and Unit Loads. |
| 30 | ASTM-D5276-98 | | Test Method for Drop Test of Loaded Container by Free Fall |
| 31 | ASTM-D5487-98 | | Test Method for Shock Test of Packaged Product. |
| 32 | ISO2859-1 | 2011 | Sampling procedures for inspection by attributes —Part 1:Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection |
| 33 | EN ISO 14644-1 | 2015 | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015) |
| 34 | EN 17141 | 2020 | Cleanrooms and associated controlled environments — Biocontamination control |

Name and Signature：Mr.Zhang Deman张德满　　Position: General Manager

Date and Place: 26th April,2023

Hefei,Anhui,China