

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: Standard Surgical Gown

Basic UDI-DI: 697527551SURGown0018A EMDN Code: T020401

Models: GS010,GS011,GS012,GS013,GS014

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.



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	EN ISO 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

			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

