

Către Agenția Medicamentului și Dispozitivelor Medicale

**NOTIFICARE**

pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
nr. .... din .....

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** solicit  
înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri  
de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a  
producătorului **HEFEI C&P NONWOVEN PRODUCTS CO.,LTD, China:**

- Halat chirurgical steril ranforsat, mărimea S
- Halat chirurgical steril ranforsat, mărimea M
- Halat chirurgical steril ranforsat, mărimea L
- Halat chirurgical steril ranforsat, mărimea XL
- Halat chirurgical steril ranforsat, mărimea XXL

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale ( format Excel).

Data **14.09.2023**

Semnătura



**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

|                                                                                                       |  |
|-------------------------------------------------------------------------------------------------------|--|
| Comentarii cu privire la<br>acceptul/refuzul recepționării<br>notificării, inclusiv motivul refuzului |  |
| Data/nr. de ordine atribuit notificării<br>de către Agenție (în cazul acceptării<br>recepționării)    |  |
| Numele, prenumele, funcția<br>persoanei responsabile de<br>recepționarea dosarului                    |  |
| Semnătura persoanei responsabile                                                                      |  |

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAȚIE PE PROPRIE RĂSPUNDERE**

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032,**  
**Chisinau, Republica Moldova,**

declar pe proprie răspundere, cunoscând prevederile art. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului producătorului **HEFEI C&P NONWOVEN PRODUCTS CO.,LTD, China:**

- Halat chirurgical steril ranforsat, mărimea S
- Halat chirurgical steril ranforsat, mărimea M
- Halat chirurgical steril ranforsat, mărimea L
- Halat chirurgical steril ranforsat, mărimea XL
- Halat chirurgical steril ranforsat, mărimea XXL

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția:*

*RA-Manager – Sandu Irina*

Semnătura \_\_\_\_\_



**Data 14.09.2023**



## Hefei C&P Nonwoven Products Co.,Ltd

Add:No.22Park road,Feidong new city development area,Hefei,Anhui,China

TEL:86-551-67707456 Fax:86-551-67709567

Email:info@cpnonwoven.com.cn Website:www.cpnonwoven.com.cn

### Authorization letter

We Hefei C & P Nonwoven Products Co., Ltd. located at No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China as a manufacturer, assign Dita Estfarm LLC, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 2017/745.

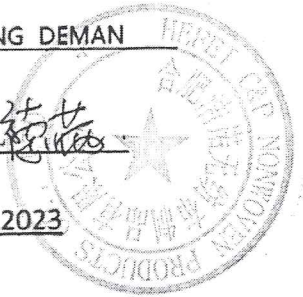
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Hefei, China

Name: ZHANG DEMAN

Signed: [Signature]

Date: 01.08.2023



# EU Certificate

Production Quality Assurance

REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A



Registration No.: DZ 2081692-1

Manufacturer: **Hefei C&P Nonwoven Products Co., Ltd.**  
No. 22 Park Road, Feidong New City Development  
Hefei, 231600 Anhui, P.R. China  
EUDAMED Single  
Registration No.: CN-MF-000002304

Products: Products of class I, sterile:  
T020401- STANDARD SURGICAL GOWNS  
- Surgical Gowns  
T020402 - REINFORCED SURGICAL GOWNS  
- Surgical Gowns  
T020199 - SURGICAL DRAPES - OTHER  
- Surgical Drapes  
T0202- SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL  
INSTRUMENT KITS)  
- Universal Surgical Packs  
T0202- SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL  
INSTRUMENT KITS)  
- Eye Surgical Packs  
T0202- SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL  
INSTRUMENT KITS)  
- Angiography Surgical Packs

The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Authorised representative(s): **SUNGO Europe B.V**  
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den  
IJssel, The Netherlands

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 244430658-200

Effective date: 2023-04-26

Expiry date: 2028-04-25

Issue date: 2023-04-26



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-091



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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

# EU Certificate

Production Quality Assurance

REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A



Registration No.: DZ 2081692-1

Manufacturer: Hefei C&P Nonwoven Products Co., Ltd.  
No. 22 Park Road  
Feidong New City Development  
Hefei  
231600 Anhui  
P.R. China

| Certificate history |                  |             |
|---------------------|------------------|-------------|
| Revision:           | Description:     | Issue date: |
| 0                   | Initial Revision | 2023-04-26  |



Report No.: 244430658-200

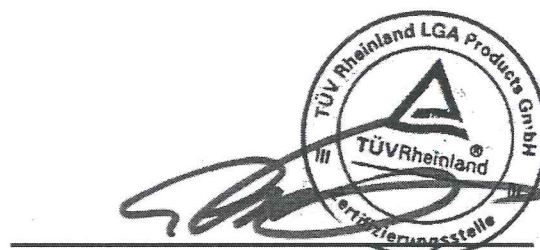
Effective date: 2023-04-26

Expiry date: 2028-04-25

Issue date: 2023-04-26



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimittel und  
Medizinprodukten  
www.zgl.de  
BS-MDR-091



Fuxiu Sheng  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

**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: Not yet

**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: Surgical Gown

Basic UDI-DI: 697527551SURGown0018A

Standard Models: GS010,GS011,GS012,GS013

EMDN Code: T020401

Reinforced Models: GR010,GR011,GR012,GR013

EMDN Code: T020402

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. :Not Yet

Issue date: Not Yet

Valid until: Not Yet

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.





CE-MDR-01-02,ver.A/0

| 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   | 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 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:

Position: General Manager

Date and Place: 10<sup>th</sup> April, 2022

| Nr. | Numărul de<br>catalog<br>(referință)* | Denumire generică (denumirea dispozitivului) | Denumire comercială (brand)* | Modelul     | Cod GMDN* |
|-----|---------------------------------------|----------------------------------------------|------------------------------|-------------|-----------|
| 1   |                                       | Halat chirurgical steril ranforsat           |                              | Mărimea S   |           |
| 2   |                                       | Halat chirurgical steril ranforsat           |                              | Mărimea M   |           |
| 3   |                                       | Halat chirurgical steril ranforsat           |                              | Mărimea L   |           |
| 4   |                                       | Halat chirurgical steril ranforsat           |                              | Mărimea XL  |           |
| 5   |                                       | Halat chirurgical steril ranforsat           |                              | Mărimea XXL |           |

