Către Agenţia Medicamentului şi 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 şi 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 acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Moraru Grigore
Date: 2023.09.16 19:30:46 EEST
Reason: MoldSign Signature
Location: Moldova

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[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producatorului 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 şi funcţia:

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:

Date: 01.08.2023

S.R.L. "DITA ESTFARM" IDNO 1002600046359 CHIŞINĂU 18

EU Certificate

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

TÜVRheinland®

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 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

TÜVRheinland®

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 Arzneimitteln und Medizinprodukten
BS-MDR-091

TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle

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.

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	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: 10th April,2022

Nr.	Numărul de catalog (referinţă)*	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