Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale
nr. 01 din 17.10.2023

Solicitantul **„MedGlobalFarm" SRL**, cu sediul **R.Moldova, mun.Chisinau, str.Miron Costin 17/7, of.71**, tel./fax: 022-523090, e-mail medglobalfarm@mail.ru, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	4AC4I-132/20	Test-indicator sterilizare 132° / 20 min extern	Sterilization Indicator Test 132C / 20min external		47783
2	4AC4I-132/20	Test-indicator sterilizare 132°/ 20 min intern	Sterilization Indicator Test 132C / 20min internal		47783
3	4AC4I-134/5	Test-indicator sterilizare 134°/ 5 min Universal	Sterilization Indicator Test 134C / 5 min Universa		47783
4	4AC4I-180	Test-indicator sterilizare 180° intern	Internal 180 sterilization test indicator		47783
5	4AC4I-180/60	Test-indicator sterilizare 180°/60 min extern	Sterilization Test Indicator 180C/ 60 min external		47783

Se anexează următoarele acte:
declaraţia de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
certificatul de conformitate CE valabil pentru dispozitivele fabricate;
actul prin care producătorul îşi desemnează reprezentantul/

Data 17.10.2023

Semnătura _____

Tabelul de recepţionare a notificării

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

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Granaci Boris
Date: 2023.10.18 12:30:24 EEST
Reason: MoldSign Signature
Location: Moldova

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producing health for the world
Dört-A Tıp Malzemeleri
Sanayi İth. İhr. Tic. Ltd. Şti.
ADRES Balıkhisar Mah.Köyiçi Serpmeleri No: 795 / A
Akyurt - ANKARA / TÜRKİYE
TEL : 0312.363 50 52-53
FAX : 0312.363 52 10
WEB : http://www.4amedical.com
E-MAİL : ankara@4amedical.com

DECLARATION OF CONFORMITY

MANUFACTURER: DÖRT-A TIP MALZEMELERİ SANAYİ İTHALAT İHRACAT TİCARET LİMİTED ŞİRKETİ

Address: Balıkhisar Mahallesi Köyiçi Serpmeleri No795A Akyurt, Ankara, Turkey

Products: Bowie Dick Test Pack, Bowie Dick A4 Sheet, Indicator Strips (H2O2 Indicator Strip, Formaldehyde Indicator Strip, Ethylene Oxide Indicator Strip, Dry heat Indicator Strip, Type 4 Indicator Strip 4ASI, Type 5 Indicator Strip, Type 6 Indicator Strip), Type 5 Integrator, Rapid Steam Biological Indicator, Longtime Steam Biological Indicator, Ethylene Oxide Biological Indicator, H2O2 (Plasma) Biological Indicator, Helix Group Tests, PCD Group Tests, Ethylene Oxide load control test, Autoclave Tapes (Steam, Ethylene Oxide, Plasma, Formaldehyde), Sterile Container System, Container Label, Container Seal, Container Filter, Surgical Instrument Protector, Documentation Labels with Indicator, Reel Barcode Labels with Indicator; Label Gun, Washer Disinfectors, Ultrasonic Devices and Washing Control Tests of Surgical Instruments (Pro Test, Hemo Tests, Washer Test, Cannula control Test, Sonicontrol Test).

Above described products complied with below norms.

DOCUMENT NO	TITLE	EDITION / DATE OF ISSUE
TS EN ISO 11140-1	Chemical Indicators	18.02.2015
TS EN ISO 11140-4	Bowie Dick Test Pack	31.01.2008
TS EN 11138-1	Biological Indicators	24.04.2017
TS EN 15883-1	Washing Machine Disinfector Residue Test	30.10.2014

Additional information: The development, production and the distribution is supported with a Quality Management System according to the requirements of the ISO 9001:2015 and ISO 13485:2016. The Quality Management System is certificated through the notified body ROYALCERT (Certificate No: 108 / DOR09B and 108 / DOR13A)
Products are Class I

If no changes made Declaration of Conformity will remain valid.

On 18th July, 2023 at Ankara, Turkey
Canan Öktem
General Manager

4a medical

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Dört A Tıp Malzemeleri San. İth. İhr. Tic. Ltd. Şti.

Company Address : Balıkhisar Mah. Köyiçi Serpmeleri No:795/A Akyurt ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product :
- Sterile/ Non-sterile Polypropylene Mesh - Class IIb
- Sterile/ Non-sterile Esu Pencil - Class IIb
- Sterile/ Non-sterile T Drain - Class IIa
- Sterile/ Non-sterile PVC Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Straight Drain (normal- blue x-ray line) - Class IIa
- Sterile/ Non-sterile PVC Thorax Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Thorax Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Flat Drain (normal/ blue x-ray line) - Class IIa
- Sterile/ Non-sterile PVC Redon Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Redon Drain (blue x-ay line) - Class IIa
- Sterile/ Non-sterile Channel Drain (normal/ blue x-ray line) (Flat/ round) - Class IIa
- Sterile/ Non-sterile Drain Suction Set (Yanquer Set) With vacuum / Without vacuum - Class IIa
- Sterile/ Non-sterile Penrose Drain (blue x-ray line) - Class IIa
- Sterile/ Non-sterile Silicone Hemovac Drain Set Single/ Double - Class IIa
- Sterile/ Non-sterile PVC Hemovac Drain Set Single / Double - Class IIa
- Sterile/ Non-sterile Esu Pencil Cleaner - Class Is
- Sterile/ Non-sterile Aspiration Tube - Class Is
- Sterile/ Non-sterile Passive Chest Drainage Bottle 2000ml - Class Is
- Sterile/ Non-sterile Bomb Reservoir - Class Is
- Sterile/ Non-sterile Aspiration Handle (Yanquer Handle) (With vacuum / Without vacuum) - Class IIa

GMDN : 44681, 60300, 35824, 11305, 11301, 35917, 44643

Certificate Number : M.2016.106.7276

Report Number : MD.3334-YB

Initial Assessment Date : 31.07.2012

Registration Date : 05.12.2016

Recertification Assessment Date : 30.11.2020

Reissue Date : 29.04.2021/02

Revision Date /No : -

Expiry Date : 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemitd.com.tr www.udem.com.tr

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TEL : 0312.363 50 52-53
FAX : 0312.363 52 10
WEB : http://www.4amedical.com
E-MAIL : ankara@4amedical.com

LETTER OF AUTHORISATION

To whom it may concern,

We;

Dört-A Tıp Malzemeleri San.İth.Ihr.Tic.Ltd.Sti.
Balıkhisar Mahallesi Köyiçi Serpmeleri no: 795 A Akyurt Ankara Turkey

Tel: +90 312 363 50 52 /53 Fax: +90 312 363 52 10

Here by confirm that, below mentioned company:

MED GLOBALFARM SRL
Address: Str. Miron Costin 17 / 7 of 71, Chişinau,2068, Moldova

Is our distributor to attend this tender no 21091458 and supply 4A Medical brands for medical applications in the territory of Moldova.

This letter of authorization is valid for 2 year and can be cancelled upon notice of 3 months by one of the parties, at any time.

06.10.2023

Canan Oktem, General Manager

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA

4a medical Dört-A Tıp Malzemeleri Sanayi İth.İhr.Tic.Ltd.Şti.

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Medglobalfarm SRL, cu sediul mun.Chişinău, str. Miron Costin 17/7,of.71,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

Test-indicator sterilizare 132° / 20 min extern

Test-indicator sterilizare 132°/ 20 min intern

Test-indicator sterilizare 134°/ 5 min Universal

Test-indicator sterilizare 180° intern

Test-indicator sterilizare 180°/60 min extern

Sunt autentice şi corespund realităţii.

Director general Granaci Boris

Semnătura

Data 17.10.2023