Digitally signed by Granaci Boris
Date: 2023.09.15 14:14:48 EEST
Reason: MoldSign Signature
Location: Moldova

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. 02 din 08.09.2023

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	SD-04703-23	Cearşaf chirurgical u/f 240*140cm	Surgical sheet "U" Split Drape 240*140cm		47783
2	SD-04205-23	Cearşaf laparoscopic 240/140x300(200+100) cm, steril	Sterile Flat Pouch SMS Laparoscopy Drape including leg covers, abdominal fenestration 25x25 cm, 6 cable holder240/140x300(200+100) cm		47783
3	SD-04209-14	Cearşaf medical 200*160 cm (steril)	Sterile Plain Drape, SS 30 gsm in flat sterilization pouch 200*160 cm		47783
4	SD-04803-23	Cearşaf TUR 250x200 cm	TUR Drape, sterile in flat pouch, with pouch and pouch with funnel, hole including finger glove, Drape include 2 leg covers - 200x250 cm		47783
5	SG-02222-04	Halat chirurgical eurostandard XL ranforsat	Reinforced Surgical Gown XL + 2 Towels + wrapping		47783
6	SG-02222-05	Halat chirurgical eurostandard XXL ranforsat	Reinforced Surgical Gown XXL + 2 Towels + wrapping		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 08.09.2023

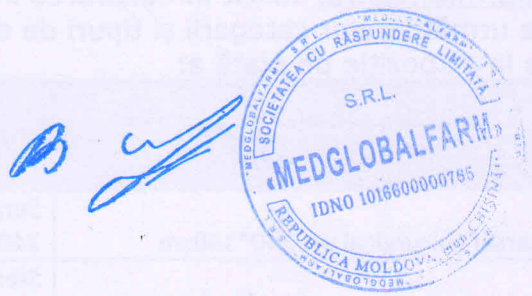
Semnătura _____

S.R.L. „MEDGLOBALFARM" IDNO 1016600000765 REPUBLICA MOLDOVA, mun. CHIŞINĂU

Tabelul de recepţionare 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	



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 08.09.2023

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	NP-01010-24	Cearşaf jetabil pentru investigatii (rulou igienic) 80cmx200m	Non Sterile Bed Sheet 80cmx200m		47783
2	NP-01010-25	Cearşaf medical 200*100 cm	Non sterile Bed cover - single packed - 100x200 cm		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 08.09.2023 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	

DECLARATION OF CONFORMITY

MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş

Organize Sanayi Bölgesi 19 Nolu Cad. No:9 MERKEZ / KİLİS
Tel: 0342 337 30 30
Fax: 0342 337 30 35

PRODUCTS : **Sterile Gowns, Drapes and Sets**

NOTIFIED BODY : **KİWA BELGELENDİRME HİZMETLERİ A.Ş. ITOSB 9.CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL - TÜRKİYE**

ID NO : **1984**

CERTIFICATION NO : **M 5035.3**

CLASSIFICATION : Class IS Rule 1 MDD 93/42/ECC Annex IX

EXECUTED ANNEX : MDD 93/42/ECC (For all versions).

ANNEXV : Conformity Assessment Route.

APPLIED STANDARDS : EN ISO 13485:2016, ISO 14971:2012, EN ISO 11135:2014, EN556-1:2001/AC:2006, EN ISO 15223-1:2012, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 14644, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, EN 13795:2011+A1:2013, EN 1041:2008+A1:2013, EN ISO 11607-1:2009+A1:2014, EN ISO 11607-2:2006+A1:2014, EN ISO 19011:2011, BS EN 62366-1:2015

APPLICATION : The directive for our product is the Council Directive 93/42 / EECfor all versions of medical devices.The Manufacturer of the product, Bayteks Teknik Tekstil San. And Tic. A.Ş, is responsible for the requirements of this council directive. Our products are not medical devices that contains human blood derivatives, animal products, animal skin, tissues, or blood derivatives or phthalates.

STERILE PRODUCTS

#	Product Name	Ref Code	Size	GMDN Code
1	U split Drape	SD-04703-23	140x240 cm	47783
2	Camera Cover	SU-40011-01	14x250 cm	47783
3	Laparoscopy Drape	SD-04205-23	240/140x300 cm	47783
4	Plain Drape	SD-04209-14	160x200 cm	47783
5	Side Adhesive Drape	SD-04204-19	70x100 cm	47783
6	Side Adhesive Drape	SD-04204-23	175x175 cm	47783
7	TUR Drape	SD-04803-23	200x250 cm	47783
8	Fenestrated Adhesive Drape	SD-04210-04	75x90 cm	47783
9	Instruments Table Cover	SD-00200-23	150x240 cm	47783
10	Eurostandard Reinforced Gown	SG-02222-04	XL	35778

11	Eurostandard Reinforced Gown	SG-02222-05	XXL	35778
12	Standard Surgical Gown	SG-01201-01	S	35778
13	Standard Surgical Gown	SG-01201-02	M	35778
14	Standard Surgical Gown	SG-01201-03	L	35778
15	Standard Surgical Gown	SG-01201-04	XL	35778
16	Standard Surgical Gown	SG-01201-05	XXL	35778
17	Reinforced Surgical Gown	SG-02202-01	S	35778
18	Reinforced Surgical Gown	SG-02202-02	M	35778
19	Reinforced Surgical Gown	SG-02202-03	L	35778
20	Reinforced Surgical Gown	SG-02202-04	XL	35778
21	Reinforced Surgical Gown	SG-02202-05	XXL	35778

The products listed in the list above and their contents are classified Class 1 Sterile products. These products ,their content, and their accessories do not take part in any other class.We herewith declare that the above mentioned products conforms general requirements of the Council Directive 93/42/EEC for all versions of Medical Device Directive .

the declaration of conformity is issued under the sole responsibility of the manufacturer.

Applied Directives

Medical Device Directive MDD 93/42/EEC (incl. 2007/47/EC) ANNEX V ALL VERSIONS.

DATE OF ISSUE : **16.09.2020**
REV.NO. : **3**
NAME AND SURNAME : **Komi Spero HEGBE**
POSITION : **FOREIGN TRADE SPECIALIST**
SIGNATURE AND STAMP :

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
MEDGLOBALFARM
IDNO 1016000000
REPUBLICA MOLDOVA

BAY TEKS
TEKNİK TEKSTİL SAN. VE TİC. A.Ş.

baymed®
"we work for your health"

Declaration of Conformity to the EU Medical Device Regulation 2017/745

Manufacturer Name(*)	Bayteks Teknik Tekstil San. Ve Tic. A.Ş.		
Manufacturer Address(*)	Organize Sanayi Bölgesi, 19 Nolu Cad. No:11/2 Merkez/KİLİS		
Manufacturer Individual Identity No.			
If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address(* If Any)	The product is produced by the manufacturer.		
Product group	Sterile without function , non sterile		
Product Name (*)	Non steril Surgical gowns and drapes		
Descriptive Information and Explanations of the Product (*)	Presented in the attached list.		
Conformity Assessment Procedure(*) **(Attachments carried out in product assessment are marked)**	■	ANNEX-IV (ANNEX II & III)	Declaration of Conformity
	☐	ANNEX-IX (CHAPTER I & III)	Quality management system
	☐	ANNEX-IX (CHAPTER II)	Technical Documentation Mod.
	☐	ANNEX-X	Type Examination
	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	ANNEX-XI (PART B)	Product Verification
Notified Body Name and Number (**)	-		
EU Certificate Number and Description Initial/Validity date (**)	-		
Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies	-		

(*)Sections beginning with are required.
(**)The conformity assessment is mandatory for products made by the notified body.

S.R.L. MEDGLOBALFARM IDNO 1016600000765 REPUBLICA MOLDOVA

baymed®
"we work for your health"

Bayteks Teknik Tekstil San. and Tic. Inc. As a company, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices.

SIGNATURE DATE AND PLACE : **25.07.2022 – Merkez/KİLİS**

EFFECTIVE DATE (IF ANY) : **-**

SIGNATORY : **Ünzile KALENDEROĞLU**

POSITION : **MANAGER**

This EU Declaration of Conformity covers ONLY products with the following catalog/reference numbers:

	PRODUCTS NAME	REF CODE	UDI	BASİC UDI-DI
1	Bed Cover – 80x200 cm	NP-01010-24	8681744101509	86817441NS3010000008083E
2	Bed Cover – 100x200 cm	NP-01010-25	8681744101509	86817441NS3010000008083E
3	Plain drape – 150x200 cm	SD-04209-11	8681744101509	86817441NS3010000008083E
4	Plain drape – 50x40 cm	SD-04209-23	8681744101509	86817441NS3010000008083E
5	Patient Gown - S	NP-02102-01	8681744101509	86817441NS3010000008083E
6	Patient Gown - M	NP-02102-02	8681744101516	86817441NS3010000089747
7	Patient Gown - L	NP-02102-03	8681744101530	86817441NS3010000089645
8	Patient Gown - XL	NP-02102-04	8681744101547	86817441NP30100001808Y3
9	Patient Gown - XXL	NP-02102-05	8681744101523	86817441NS3010000008994B
10	Patient Gown - XXXL	NP-02102-06	8681744101523	86817441NS3010000008994B

MEDGLOBALFARM S.R.L. SOCIETATE CU RASPUNDERE LIMITATA S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA BIROUL CHISINAU

BAY TEKS
TEKNİK TEKSTİL SAN. VE TİC. A.Ş.
Merkez Başpınar Organize Sanayi Bölgesi 83207 Nolu Cad. No 2 Şehitkamil / GAZİANTEP
Fabrika Org. San. Bol. 19 Nolu Cad. No 1 Merkez / KİLİS
Mersis No 0159003874400017 Ticaret Sicil No 54567
Şehitkamil Vergi Dairesi Vergi No 1590038749

CERTIFICATE

kiwa

EC Certificate
Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-18-479

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ

Organize Sanayi Bölgesi 19 nolu Cad. No:9 Merkez / Kilis - Turkey

Products: Sterile Disposable Surgical Gown, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.5035.03
Date of first issue:	12 January 2018
Date of last issue:	16 September 2020
Revision Number:	03
Expiry Date:	27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

16 September 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

S.R.L. GLOBALFARM IDNO 1016600000765 REPUBLICA MOLDOVA

BAYDIŞ

January 02, 2023.

To:

MEDGLOBALFARM SRL.

Company Address :

Mun.Chisinau, str.Miron Costin-17/2
Cod postal-2068 ; TVA 0609048
MOLDOVA

Authorization Letter

This authorization letter is dated on the **02 January 2023**;

BAYDIS TİCARET A.Ş.

Here in after refer to as " **The Exporter**" with its principal Office at

Başpınar O.S.B. Mh. O.S.B. 5. Böl. 83514 Nolu Cad. No. 18 Şehitkamil /Gaziantep Turkey
Tel : +90 348 832 10 60 (Pbx)
Fax: +90 348 834 10 28

Exporter of BAYMED products range manufactured by **BAYTEKS TEKNİK TEKSTİL SANAYİ ve TİCARET A.Ş.** defined as:

1. **Disposable Surgical Drape,**
2. **Disposable Surgical Gowns and**
3. **Disposable Surgical Packs;**

Hereby authorizes

MEDGLOBALFARM SRL.

Herein after refer to as "**The Distributor**"; with its principal place of business at

Mun.Chisinau, str.Miron Costin-17/2
Cod postal-2068 ; TVA 0609048
MOLDOVA

To be our **distributor** in **Moldova** (herein after refer to as "**The Territory**") and carry out every registration needed by our products.

We certify that **The Distributor** has been appointed as **the distributor** and marketing holder for **BAYMED products range** of **The Exporter.**

BAYDIŞ

We here with appoint an authorize **The Distributor** to be the agent for the registration, import, marketing and selling of our **BAYMED products range.**

This authorization letter is limited to the procedures in **The Territory, The Distributor** is not entitled to sub-delegate these tasks and to authorize any other person on the behalf of **The Exporter**.

This letter is effective starting until the end of December 2025.
The present letter can be terminated any time with a one-month's written notice period.

Authorised Signatory:

Name: Ece GÜRBÜZ

Job Title: Foreign Trade Manager

Signature:

BAY DIŞ TİCARET A.Ş.

Date: January 02,2023

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDGLOBAL IDNO 1018600000185 REPUBLICA MOLDOVA

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:

Cearşaf chirurgical u/f 240*140cm

Cearşaf laparoscopic 240/140x300(200+100) cm, steril

Cearşaf medical 200*160 cm (steril)

Cearşaf TUR 250x200 cm

Halat chirurgical eurostandard XL ranforsat

Halat chirurgical eurostandard XXL ranforsat

Cearşaf jetabil pentru investigatii (rulou igienic) 80cmx200m

Cearşaf medical 200*100 cm

Sunt autentice şi corespund realităţii.

Director general Granaci Boris

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA, mun. CHIŞINĂU

Semnătura _____

Data 08.09.2023