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	SD-01601-03	Câmpuri operatorii pentru chirurgia globului ocular 6x4 cm, SMS	Baymed Sterile Ophthalmic Surgical Drape	Sterile Ophthalmic Surgical Drape	47783
2	SD-01601-24	Câmpuri operatorii pentru chirurgia globului ocular 6x4 cm, SMS Laminat	Baymed Sterile Ophthalmic Surgical Drape	Sterile Ophthalmic Surgical Drape	47783
3	SD-01601-25	Câmpuri operatorii pentru chirurgia globului ocular, 10x12 cm, SMS	Baymed Sterile Ophthalmic Surgical Drape	Sterile Ophthalmic Surgical Drape	47783
4	SD-01601-26	Câmpuri operatorii pentru chirurgia globului ocular, 10x12 cm, SMS Laminat	Baymed Sterile Ophthalmic Surgical Drape	Sterile Ophthalmic Surgical Drape	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 26.09.2023 Semnătura _____

«MEDGLOBALFARM» IDNO 1016600000765

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: 2023.09.29 14:34:31 EEST
Reason: MoldSign Signature
Location: Moldova

baymed®
"we work for your health"

DATE	16.09.2020
DOC. NO	TS-02
PAGE NO	Sayfa 1 / 2
REV.NO	3
REV.DATE	10.09.2018

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	Ophthalmic Drape SMS	SD-01601-03	100x120 cm	47783
2	Ophthalmic Drape 2ply	SD-01601-24	100x120 cm	47783
3	Ophthalmic Drape SMS	SD-01601-25	100x120 cm	47783
4	Ophthalmic Drape 2ply	SD-01601-26	100x120 cm	47783

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.

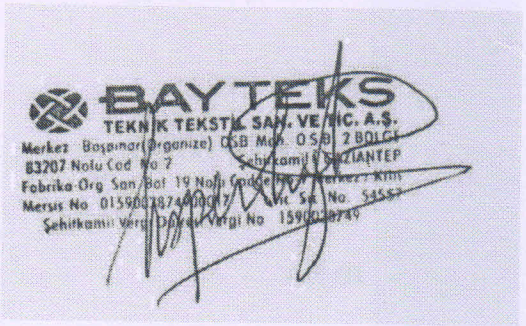
the declaration of conformity is issued under the sole responsibility of the manufacturer.

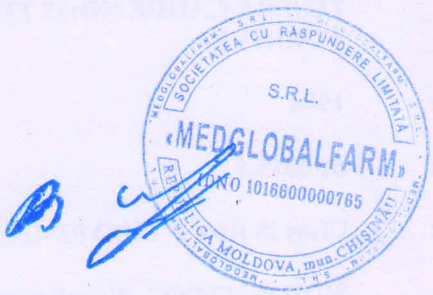
MEDGLOBALFARM S.R.L. IDNO 1016600000765

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 :





CERTIFICATE

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

Muhteşem Gökhan Yücel
Head of Notified Body

16 September 2020, Istanbul, Turkey

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. MEDGLOBALFARM 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.**

MEDGLOBALFARM S.R.L. IDNO 1016000000765 REPUBLICA MOLDOVA

BAY DIŞ TICARET A.Ş.

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.
Başpınar (Organize) O.S.B Mah. O.S.B 4. Bölge
83404 Nolu Cad. No:15 Şehitkamil/GAZİANTEP
Tel.: 0 348 822 10 60 Fax: 0 348 834 10 28
Mersis No: 0150 0909 8610 0001
Tic.Sic.No.54559

Date: January 02,2023

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
«MEDGLOBAL»
IDNO 1016600000765
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:

Câmpuri operatorii pentru chirurgia globului ocular 6x4 cm, SMS
Câmpuri operatorii pentru chirurgia globului ocular 6x4 cm, SMS Laminat
Câmpuri operatorii pentru chirurgia globului ocular, 10x12 cm, SMS
Câmpuri operatorii pentru chirurgia globului ocular, 10x12 cm, SMS Laminat

Sunt autentice şi corespund realităţii.

Director general Granaci Boris

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765

Semnătura _____

Data 26.09.2023