

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

Către Agenția Medicamentului
și 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 și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	SP-05006-68	Set steril getabil pentru interventii (pacemaker)	BAYMED STERILE PACEMAKER PACK	STERILE PACEMAKER PACK	47783
2	SP-05006-67	Set steril getabil pentru interventii (electrofiziologie)	BAYMED STERILE ELECTROPHYSIOLOGY PACK	STERILE ELECTROPHYSIOLOGY PACK	47783

Se anexează următoarele acte:

declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
certificatul de conformitate CE valabil pentru dispozitivele fabricate;
actul prin care producătorul își desemnează reprezentantul/

Data 26.09.2023

Semnătura

Granaci

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	



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

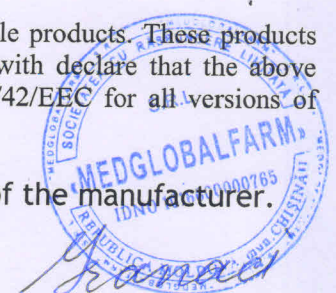
APPLICATION : The directive for our product is the Council Directive 93/42 / EECfor all
versions of medical devices.The Manufacturer of the product, Bayteks Teknik Tekstil San. And Tic. A.Ş, is
responsible for the requirements of this council directive. Our products are not medical devices that contains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

STERILE PRODUCTS

#	Product Name	Ref Code	Size	GMDN Code
1	Pacemaker Pack	SP-05006-68	STD	47783
2	Electrophysiology Pack	SP-05006-67	STD	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.





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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.

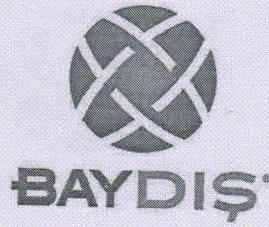
Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhtesem Gökhan Yücel
Head of Notified Body

16 September 2020, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 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





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.

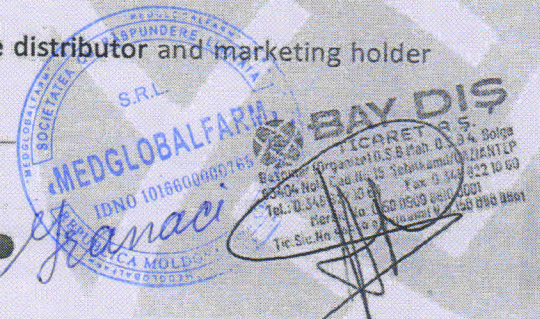
We certify that The Distributor has been appointed as the distributor and marketing holder for BAYMED products range of The Exporter.

BAY DIŞ TİCARET A.Ş.

Başpınar(Organize) O.S.B. Mh. O.S.B. 2. Bölge 83211 Nolu Cad. No. 3 Şehitkamil / GAZİANTEP
+90 348 822 10 60 +90 348 834 10 28

Şehitkamil V.D. 150 090 9861 - Mersis No. 0150 0909 8610 0001 - Tic. Sic. No. 54559

BAY DIŞ TİCARET A.Ş. HASKAN ŞİRKETLER GRUBU KURULUŞUDUR.





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.

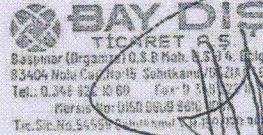
The present letter can be terminated any time with a one-month's written notice period.

Authorised Signatory:

Name: Ece GÜRBÜZ

Job Title: Foreign Trade Manager

Signature:



Date: January 02, 2023



BAY DIŞ TİCARET A.Ş.

Baspinar(Organize) O.S.B. Mah. O.S.B. 2. Bölge 83211 Nolu Cad. No. 3 Şehitkamil / GAZİANTEP
+90 348 822 10 60 ☑ +90 348 834 10 28
Şehitkamil V.D. 150 090 9861 - Mersis No. 0150 0909 8610 0001 - Tic. Sic. No. 54559

BAY DIŞ TİCARET A.Ş.  HASKAN ŞİRKETLER GRUBU KURULUŞUDUR.

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al
Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate
pentru notificarea dispozitivului medical:

1. Set steril getabil pentru intervenții (pacemaker)
2. Set steril getabil pentru intervenții (electrofiziologie)

Sunt autentice și corespund realității.

Director general Granaci Boris



Semnătura Granaci

Data 26.09.2023