DNV·GL

Ms. Harsoria Healthcare Pvt. Ltd.
110-111, PHASE-IV, UDYOG VIHAR,
GURGAON -122015, HARYANA, INDIA.

DNV GL Business Assurance
India Pvt. Ltd.
Equinox Business Park, Tower 3,
6th Floor, LBS Marg,
Kurla (West), Mumbai-400070,
India

Date:	**Our reference:**	**Your reference:**
27-Feb-2019	NA	Email dated 24th February 2020

Sub: Clarification regarding status of CE certification.

Dear Sir/Madam,

This is regarding the email received from you dated 24th Feb 2020 requesting to seek clarification on the status of CE certification, issued by Presafe (a DNV GL Company) vide No. 11168-2017-CE-IND-NA-PS Rev. 0.0 valid until 04th March 2020. It is confirmed that, as per our records, the said certificate is issued by Presafe.

Recertification audit for the products mentioned in the said CE certificate having Number 11168-2017-CE-IND-NA-PS Rev. 0.0 has been successfully conducted and the Audit team has recommended DNV GL Presafe AS, the Notified Body, to grant the recertification for the existing CE certificate.
The assessment reports for all the products are under the Technical Review with DNV GL Presafe AS, Norway. On successful completion of Technical Review, by the Notified Body, the CE certificate will be issued.

for DNV GL Business Assurance India Pvt. Ltd.

Joher Jerwalla
Business Head – Product Assurance
DNVGL - Business Assurance.
E-mail: joher.jerwalla@dnvgl.com

MDD EXTENSION APPROVAL LETTER

23.05.2024

To whom It May Concern,

As UDEM A.Ş., operating as a notified body within the scope of the 93/42/EEC Medical Device Regulation, we have issued an EC certificate on the date 27.04.2020 within the scope of the 93/42/EEC Medical Device Directive for the company and products whose information is given in Table-1. We declare that the certificate is valid for the products given in Table-1 before the expiry date of the relevant certificate.

Table-1

Company Name	EC Certificate No	Scope	Expiry Date
DLR Medikal San. ve Dış Tic. Ltd. Şti.	M.2016.106.7244 M.2016.106.7244-1	-Sterile Long Term Haemodialysis Catheter, Kits and Accessories -Sterile Short Term Haemodialysis Catheter, Kits and Accessories	27.05.2024

In order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates within the scope of the Regulation on the Amendment of the Medical Device Regulation published in the Official Gazette dated 02 April 2023 and numbered 32151, UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 9342EEC has been provided from the relevant company. When the information provided by the company is reviewed, it has been shared that an application has been made to another notified body authorized under (EU) 2017/745 for the products given in Table-2 within the scope of the said EC certificate and/or the devices intended to replace it and/or a contract has been signed with the relevant notified body.

Table-2

Device	MDR NB	Date of Application	Date of Contract
-Sterile Long Term Haemodialysis Catheter, Kits and Accessories -Sterile Short Term Haemodialysis Catheter, Kits and Accessories	2975	13.05.2024	-

In accordance with the Regulation Amending the Medical Device Regulation, for the products listed in Table-2, which are within the scope of the EC certificate for the above-mentioned company and are also under the MDR contract, unless undertaken by the other notified body after the MDR contract, we declare that we have undertaken the surveillance audit responsibility until 26 September 2024 with UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates signed by the relevant company and UDEM A.Ş. on 23.05.2024 as specified in Article 120 (3e) of the relevant Regulation. As of 26.05.2024, we do not have any surveillance responsibility for products that are within the scope of EC certificate but do not have an MDR application/contract.

The execution of the said surveillance audits will continue depending on the company's fulfillment of the obligations set forth in Article 120 (3c) of the relevant Regulation.

Serian DOMA
Medical Device Technical Regulation Responsible

DİRME
A.Ş.
Mutlukent Mah. 2079. Sok. No: 10
Ümitköy-Çankaya / ANK. Tel:(0312) 443 03 90
Doğanbey Vergi Dairesi 885 044 2587

DLR Medikal
San. ve Dış Tic. Ltd. Şti.

DLR MEDİKAL

Üretici Beyanı / Manufacturer's Declaration

(AB) 2017/745 ve (AB) 2017/746 sayılı Tüzükleri belirli tıbbi cihazlar ve in vitro diagnostik tıbbi cihazlar için geçiş hükümleri bakımından tadil eden (AB) 2023/607 sayılı Tüzük ile ilgili olarak, özellikle

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- Vücuda Yerleştirilebilir Aktif Tıbbi Cihazlara (AIMDD) ilişkin 90/385/EEC sayılı Konsey Direktifi veya Tıbbi Cihazlara (MDD) ilişkin 93/42/EEC sayılı Konsey Direktifi (Direktif Sertifikaları) kapsamında verilen sertifikaların geçerliliği ve/veya

  The validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or

- cihazların ve bunların üreticisi olarak bizim, piyasaya sürülmeye ve hizmete sunulmaya devam edilmesine ilişkin koşullara uygunluğumuz

  The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Üretici Adı/ ***Manufacturer name***	DLR MEDİKAL SAN. Ve DIŞ TİC.LTD.ŞTİ.
Üretici adresi ve iletişim bilgileri ***Manufacturer address and contact details***	Şerifali Mah. Beyan Sok.No:36/A Ümraniye İSTANBUL/TÜRKIYE
Tekil Kayıt Numarası (SRN) (varsa) ***Single Registration Number (SRN) (if available)***	TR-MF-000024447

Yetkili Temsilci adı (varsa) ***Authorised Representative name (if applicable)***	
Yetkili Temsilci adresi ve iletişim bilgileri ***Authorised Representative address and contact details***	
Tekil Kayıt Numarası (SRN) (varsa) ***Single Registration Number (SRN) (if available)***	

Onaylanmış kuruluş adı (varsa) ***Notified body name (if applicable)***	UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Onaylanmış kuruluş numarası (varsa) ***Notified body number (if applicable)***	2292
Direktif Sertifika numarası(ları) bu onayın yapıldığı (varsa) ***Directive Certificate number(s) to which this confirmation is made (if applicable)***	VASKULER CE SERTİFİKA NUMARASI *VASCULAR CE CERTIFICATE NUMBER:* M.2016.106.7244 UROLOJİ CE SERTİFİKA NUMARASI: *UROLOGY CE CERTIFICATE NUMBER*: M.2016.106.6518
Geçerlilik süresinin uzatılmasından önce Direktif Sertifikasında belirtilen orijinal son kullanma tarihi (varsa)	27.05.2024

DLR Medikal
San. ve Dış Tic. Ltd. Şti.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	
Uzatılmış geçerlilik/geçiş döneminin bitiş tarihi ***End date of extended validity/transition period***	Kısa Dönem Hemodiyaliz Kateter ve Seti ve Uzun Dönem Hemodiyaliz Kateter ve Seti / *Short Term Hemodialysis Catheter and Set and Long Term Hemodialysis Catheter and Set*:12-2027 Üreteral Stent ve seti / *Ureteral Stent and set*:: 12-2028

Biz, DLR Medikal olarak kendi sorumluluğumuz altında beyan ederiz:

We, DLR Medikal, declare under our own responsibility:

- Yukarıda listelenen **Direktif Sertifikası** için (veya birden fazla sertifika varsa ekteki çizelgeye bakınız) MDR Madde 120.2'de istenen yasal geçerlilik süresi uzatımı koşullarının karşılandığını ve/veya

  *for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or*

- Ekteki çizelgede **listelenen cihaz(lar)** ve bunların üreticisi olarak biz, piyasaya sürülmeye ve hizmete sunulmaya devam edilmesi için MDR Madde 120.3c'de listelenen koşullara uygunluğunu,

  *the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,*

yani aşağıdaki koşulları yerine getirerek/ *namely by fulfilling the following conditions*:

- Uygunluk değerlendirmesi için Ek VII MDR'nin Bölüm 4.3, birinci alt paragrafına uygun olarak onaylanmış kuruluşa resmi başvuru(lar), ekli çizelgede listelenen cihaz(lar) veya yedek(ler)i için en geç 26 Mayıs 2024 tarihine kadar tarafımızdan bir onaylanmış kuruluşa yapılmıştır veya yapılacaktır ve 26 Eylül 2024 tarihinden önce Ek VII MDR'nin Bölüm 4.3, ikinci alt paragrafına uygun olarak imzalanmış yazılı anlaşma(lar) mevcuttur/olacaktır.
  Formal application(s) to the notified body in accordance with Section 4.3, first subpara-graph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- MDR Madde 10(9) uyarınca bir KYS, en geç 26 Mayıs 2024 tarihine kadar uygulamaya konulacaktır.
- *A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.*

- ➢ Ekteki programda listelenen cihaz(lar)
- ❗ Cihaz(lar) AIMDD veya MDD ile uyumlu olmaya devam eder.
- ❗ Tasarımda ve kullanım amacında önemli bir değişiklik yoktur.
- ❗ Cihaz(lar), hastaların, kullanıcıların veya diğer kişilerin sağlığı veya güvenliği veya halk sağlığının korunmasına ilişkin diğer hususlar açısından kabul edilemez bir risk oluşturmaz.
- ➢ ***Device(s) as listed in the attached schedule***

- ❗ *The device(s) continue to comply with the AIMDD or MDD.*
- ❗ *There are no significant changes in the design and intended purpose.*
- ❗ *The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.*

DLR MEDİKAL SAN. VE DIŞ TİC. LTD.ŞTİ
TÜRKİYE-TURKEY /13.02.2024
KALİTE YÖNETİM TEMSİLCİSİ/ QUALITY MANAGEMENT REPRESENTATIVE

SEVDA KOCAMAN
sevda@dlrmed.com

DLR Medikal
San. ve Dış Tic. Ltd. Şti.

Cihaz Programı / ***Schedule of Devices***

Yukarıdaki Üretici Beyanı aşağıdaki cihazlar için geçerlidir/
The above Manufacturer's Declaration is valid for the following devices:

Cihaz(lar)ın tanımlanması (örn. cihaz adı, aile/grup adı cihaz modeli veya katalog numarası) ***Identification of the device(s)*** *(e.g., device name, family/group name device model or catalogue number)*	**Direktif Sertifika numarası/numaraları bu onayın yapıldığı kişi** (varsa) ***Directive Certificate number(s) to which this confirmation is made*** *(if applicable)*	**Geçerlilik süresinin uzatılmasından önce Direktif Sertifikalarında belirtilen orijinal son kullanma tarihi** (uygunsa) ***Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity*** *(if applicable)*	**Direktif Sertifikasını düzenleyen Onaylanmış Kuruluşun adı ve numarası** (uygunsa) ***Notified Body name and number that issued the Directive Certificate*** *(if applicable)*	**MDR başvurusunun yapıldığı/sözleşmenin imzalandığı Onaylanmış Kuruluşun adı ve numarası** (uygunsa) ***Notified Body name and number where the MDR application was lodged/contract signed*** *(if applicable)*	**Uzatılmış geçerlilik / geçiş döneminin bitiş tarihi** ***End date of extended validity / transition period***	**Yedek Cihaz(lar)** (uygunsa) ***Substitute Device(s)*** *(if applicable)*
UZUN DÖNEM HEMODİYALİZ KATETERİ VE SETİ ***LONG TERM HEMODIALYSIS CATHETER AND SET***	**M.2016.106.7244**	**27.05.2024**	**UDEM 2292**	**SZUTEST Konfomitätsbewertungsstelle GmbH /2975**	**12-2027**	
KISA DÖNEM HEMODİYALİZ KATETER SET VE AKSESUARLARI ***SHORT TERM HEMODIALYSIS CATHETER AND SET***	**M.2016.106.7244**	**27.05.2024**	**UDEM 2292**	**SZUTEST Konfomitätsbewertungsstelle GmbH /2975**	**12-2027**	
ÜRETERAL STENT VE SET ***URETERAL STENT AND SET***	**M.2016.106.6518**	**27.05.2024**	**UDEM 2292**	**SZUTEST Konfomitätsbewertungsstelle GmbH /2975**	**12-2028**	

Şerifali Mah. Beyan Sk. No:36/A Ümraniye - İstanbul / TÜRKİYE
Tel: +90 216 316 29 69 Fax: +90 216 412 58 26 www.dlrmed.com info@dlrmed.com

CERTIFICATE

Full Quality Assurance System

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

Company Name	: DLR Medikal San. ve Dış Tic. Ltd. Şti.
Company Address	: Şerifali Mah. Beyan Sok. No:36/A Ümraniye ISTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Class IIa and Class IIb - Sterile Products - Guide Wire - Class IIa - Drainage (PCN) Catheters and Set - Class IIa - Suprapubic Catheter- Class IIa - Ureteral Catheter - Class IIa - Dilators - Class IIa - Needles - Class IIa - TURP Loops - Class IIb - Stone Basket - Class IIa - Ureteral Balloon Dilator - Class IIa - Evacuator - Class IIa - Ureteral Stent [Double J Stent) - Class IIb - Dual Lumen Ureteral Catheter - Class IIa
GMDN	: 45623, 10735, 34924, 34926, 11265, 38821, 32337, 12734, 62061, 35808, 11265, 37143, 47035, 34926

Product Types are attached.

Certificate Number	: M.2016.106.6518
Report Number	: UD.3098.YB
Initial Assessment Date	: 02.02.2016
Registration Date	: 29.03.2016
Recertification Assessment Date	: 24.10.2019
Reissue Date / No	: 04.05.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

APPROV

[redacted]ation
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 applied 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 certificate 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 returned upon 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 the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 312 443 03 77 **Fax:** +90 312 441 87 72
E-mail: info@udemltd.com.tr www.udem.com.tr

This document containing 1 (one) pages is the Annex of the Certificate with the number M.2016.106.6518 and with the registration date of 29.03.2016 and with the re-issue date 04.05.2020 issued for "DLR Medikal San. ve Dış Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

1. Guide Wire - Class IIa	GMDN	9.TURP Loops - Class IIb	GMDN
PTFE Guide Wire	45623	Cutting Loop	62061
Hydrophilic Guide Wire	45623	Cold Knife	62061
Striped Guide Wire	45623	Colling Knife	62061
Nitinol Guide Wire	45623	Roller Loop	62061
2. Drainage (PCN) Catheter and Set - Class IIa		Bipolar Loop	62061
Drainage (PCN) Catheter	10735	Ball Bipolar Loop	62061
Drainage (PCN) with Needle	10735	Ball Electrode	62061
Drainage (PCN) Catheter Set	10735	**10.Stone Basket - Class IIa**	
Drainage (PCN) Set with Needle	10735	Stone Basket Nitinol (Z)	35808
3.Suprapubic Catheter and Set - Class IIa		Stone Grasper	35808
Suprapubic Catheter Set	34924	URS Forceps	35808
Suprapubic Cysto Catheter Set	34924	PCN Basket (Perk)	35808
4.Ureteral Catheter - Class IIa	34926	**11. Ureteral Balloon Dilator - Class IIa**	
5.Dilators - Class IIa		Ureteral Balloon Dilator with Inflation Device	11265
Amplatz Dilator Sheat	11265	Nephrostomy Balloon Dilator	11265
Amplatz Dilator Set	11265	Nephrostomy Balloon Dilator with Inflation Device	11265
Braided Shaft Catheter	38821	Nephrostomy Balloon Dilator with Amplatz Sheat	11265
6.Needles - Class IIa		**12.Evacuator - Class IIa**	37143
IP Needle	32337	**13.Ureteral Stent (Double J Stent) - Class IIb**	47035
Chiba Needle	32337		
Biopsy Gun	12734		
7-Dual Lumen,Ureteral Catheter- Class IIa	34926		

APPROV

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Mutlukent Mahallesi 2073. Sokak (Eski 93 Sokak) No:10 Ümitköy – Çankaya – ANKARA
T:03124430390 F:03124430376 info@udemltd.com.tr www.udem.com.tr

ıtion
ustry
and Trade Inc. Co.

SERTIFIKATAS

Visiška kokybės užtikrinimo sistema
Medicinos prietaisų direktyva 93/42 /EEB Priedas II (išskyrus 4 skirsnį)

Įmonės pavadinimas	: DLR Medikal San. ve Dis Tic. Ltd Sti.
Įmonės adresas	: Serifali Mah. Beyan Sak. Nr. 36/A, Umranija, ISTANBULAS/TURKIJA
Susijusi Direktyva ir priedas:	: 93/42/EEB medicinos prietaisų direktyva - II priedas, išskyrus 4 skirsnį
Produktas:	IIa ir IIb klasės - sterilūs gaminiai - Viela-pravedėjas – IIa klasė - Drenavimo (PCN) kateteriai ir jų rinkiniai – IIa klasė - Suprapubiniai kateteriai – IIa klasė - Ureteriniai kateteriai – IIa klasė - Diliatoriai – IIa klasė - Adatos – IIa klasė - TURP kilpos – IIb klasė - Akmenų ištraukimo krepšeliai – IIa klasė - Ureteriniai balioniniai diliatoriai – IIa klasė - Ištraukėjas – IIa klasė - Ureteriniai stentai (dvigubi J stentai) – IIb klasė - Dviejų kanalų ureteriniai kateteriai – IIa klasė
Nomenklatūros numeris	: 45623, 10735, 34924, 34926, 11265, 38821, 32337, 12734, 62061, 35808, 11265, 37143, 47035, 34926 Produktų tipai pridėti

Pažymėjimo numeris Ataskaitos numeris Pradinio vertinimo data	: M.2016.106.6518 : UD.3098.YB : 2016 02 02
Registracijos data	: 2016.03.29
Pakartotinio sertifikavimo įvertinimo data	: 2019.10.24
Pakartotinio išdavimo data/ Nr	: 2020.05.04/01
Galiojimo data	: 2024.05.27

UDEM Tarptautinis
Sertifikavimo Audito
mokymo centras
Pramonė ir prekyba Inc.
Co

Šis dokumentas sudarytas iš vieno puslapio ir yra priedas prie Sertifikato Nr. M.2016.106.6518, kuris užregistruotas 2016.03.29 ir pakartotinai išduotas 2020.05.04 DLR Medikal San ve Dis Tic. Ltd Sti. Sertifikatą išdavė UDEM, kuris teikia Notifikuotosios įstaigos paslaugas, identifikacinis Nr. 2292, pagal Medicininių prietaisų direktyvą 93/42/EEB.

1. Viela-gidas – IIa klasė	**Nomenklatūros Nr.**	**9. TURP kilpos – IIb klasė**	**Nomenklatūros Nr.**
PTFE viela-gidas	45623	Pjaunanti kilpa	62061
Hidrofilinė viela-gidas	45623	Šalto pjovimo peilis	62061
Dryžuota viela-gidas	45623	Šaldantis peilis	62061
Nitinolinė viela-gidas	45623	Ritininė kilpa	62061
2. Drenavimo (PCN) kateteriai ir jų rinkiniai – IIa klasė		Bipolinė kilpa	62061
Drenavimo (PCN) kateteris	10735	Bipolinė rutulio formos kilpa	62061
Drenavimo (PCN) kateteris su adata	10735	Rutulio formos elektrodas	62061
Drenavimo (PCN) kateterio rinkinys	10735	**10. Akmenų ištraukimo krepšelis – IIa klasė**	35808
Drenavimo (PCN) kateterio rinkinys su adata	10735	Nitinolinis (Z) akmenų ištraukimo krepšelis	35808
3. Suprapubiniai kateteriai ir jų rinkiniai – IIa klasė		Akmenų traukėjas	35808
Suprapubinių kateterių rinkiniai	34924	URC žnyplės	35808
Suprapubinių cysto kateterių rinkiniai	34924	PCN krepšelis (Perk)	35808
4. Ureteriniai kateteriai – IIa klasė	34926	**11. Ureterinis balioninis diliatorius – IIa klasė**	
5. Diliatoriai – IIa klasė		Ureterinis balioninis diliatorius su pripūtimo prietaisu	11265
Amplatz diliatoriaus mova	11265	Nefrostominis balioninis diliatorius	11265
Amplatz diliatorių rinkinys	11265	Nefrostominis balioninis diliatorius su pripūtimo prietaisu	11265
Pintas kateteris	38821	Nefrostominis balioninis diliatorius su Amplatz mova	11265
6. Adatos – IIa klasė		**12. Ištraukėjas – IIa klasė**	37143
IP adata	32337	**13. Ureterinis stentas (dvigubas J stentas) – IIb klasė**	47035
Chiba adata	32337		
Biopsinė šaudyklė	12734		
7. Dviejų kanalų ureterinis kateteris – IIa klasė	34926		

MDD EXTENSION APPROVAL LETTER

23.05.2024

To whom It May Concern,

As UDEM A.Ş., operating as a notified body within the scope of the 93/42/EEC Medical Device Regulation, we have issued an EC certificate on the date 27.04.2020 within the scope of the 93/42/EEC Medical Device Directive for the company and products whose information is given in Table-1. We declare that the certificate is valid for the products given in Table-1 before the expiry date of the relevant certificate.

Table-1

Company Name	EC Certificate No	Scope	Expiry Date
DLR Medikal San. ve Dış Tic. Ltd. Şti.	M.2016.106.6518	Ureteral Stent (Double J Stent) - Class IIb	27.05.2024

In order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates within the scope of the Regulation on the Amendment of the Medical Device Regulation published in the Official Gazette dated 02 April 2023 and numbered 32151, UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 9342EEC has been provided from the relevant company. When the information provided by the company is reviewed, it has been shared that an application has been made to another notified body authorized under (EU) 2017/745 for the products given in Table-2 within the scope of the said EC certificate and/or the devices intended to replace it and/or a contract has been signed with the relevant notified body.

Table-2

Device	MDR NB	Date of Application	Date of Contract
Ureteral Stent (Double J Stent) - Class IIb	2975	13.05.2024	-

In accordance with the Regulation Amending the Medical Device Regulation, for the products listed in Table-2, which are within the scope of the EC certificate for the above-mentioned company and are also under the MDR contract, unless undertaken by the other notified body after the MDR contract, we declare that we have undertaken the surveillance audit responsibility until 26 September 2024 with UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates signed by the relevant company and UDEM A.Ş. on 23.05.2024 as specified in Article 120 (3e) of the relevant Regulation. As of 26.05.2024, we do not have any surveillance responsibility for products that are within the scope of EC certificate but do not have an MDR application/contract.

The execution of the said surveillance audits will continue depending on the company's fulfillment of the obligations set forth in Article 120 (3c) of the relevant Regulation.

Serian DOMA

Medical De Responsible

UDE NDİRME
Mutluk C. A.Ş.
ANKARA
Tel: (0.312) 443 03 90 (pbx) Fax: (0.312) 443 03 76
DOĞANBEY Vergi Dairesi [illegible]

CERTIFICATE

Full Quality Assurance System

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

M.2016.106.6908-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: TMT Tıbbi Medikal Malzemeleri Sanayi ve Ticaret A.Ş.
Company Address	: Fatih Mah. 1188 Sok. No: 14 Sarnıç Gaziemir İZMİR / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: 1- Spinal Anesthesia Needles - Sets - Kits - Class III - Sterile - Spinal Anesthesia Needles - Spinal Anesthesia Sets - Combined Spinal Epidural Anesthesia Sets - Combined Spinal Epidural Anesthesia Kits 2- Epidural Anesthesia Needles - Sets - Kits - Class IIa - Sterile - Epidural Anesthesia Needles - Epidural Anesthesia Sets - Epidural Anesthesia Kits - Echogenic Transforaminal Epidural Cannula with Blunt Tip - Echogenic Transforaminal Epidural Cannula with Blunt Tip Sets - Caudal Anesthesia Needles - Caudal Anesthesia Sets 3- IIntrauterine Contraceptive Device - Class III - Sterile 4- Seldinger (Angiography) Needle - Class III - Sterile 5- Biopsy and Aspiration Needles-Kits and Accessories - Class IIa - Sterile 6- Medical Accessories for Anesthesia - Class IIa - Sterile 7- Medical Accessories for Anesthesia-Class I - Sterile
GMDN	: 35212, 34845, 58293, 34842, 45178, 34841, 46920, 12747, 47540, 35886, 46350, 45018, 45316, 31245, 18069, 35795, 34916, 37040, 46115 Product Types are attached.
Certificate Number	: M.2016.106.6908
Report Number	: MD.3193.YB
Initial Assessment Date	: 16.07.2016
Registration Date	: 28.07.2016
Recertification Assessment Date	: 01.08.2019
Reissue Date / No	: 20.01.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

cation
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 applied 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 certificate 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 returned upon 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 the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

This document containing 2 (two) pages is the Annex of the Certificate with the number M.2016.106.6908 and with the registration date of 28.07.2016 and with the re-issue date 20.01.2020 issued for "TMT Tıbbi Medikal Malzemeleri Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Spinal Anesthesia Needles – Sets – Kits – Class III – Sterile	
Spinal Anesthesia Needles	**GMDN: 35212**
Quincke Type Spinal Anesthesia Needles	
Quincke Type Spinal Anesthesia Needles – with Guide	
Quincke Type Spinal Anesthesia Needles – with Filtered Aspiration Cannula	
Quincke Type Spinal Anesthesia Needles – with Guide and Filtered Aspiration Cannula	
Atraumatic-Pencil Point Spinal Anesthesia Needles	
Atraumatic-Pencil Point Spinal Anesthesia Needles – with Guide	
Atraumatic-Pencil Point Spinal Anesthesia Needles – with Filtered Aspiration Cannula	
Atraumatic-Pencil Point Spinal Anesthesia Needles – with Guide and Filtered Aspiration Cannula	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles – with Guide	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles – with Filtered Aspiration Cannula	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles – with Guide and Filtered Aspiration Cannula	
Spinal Anesthesia Sets	**GMDN: 34845**
Spinal Anesthesia Set with Quincke Type Spinal Anesthesia Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Hypodermic Needle, Waste Needle Box, Square Plaster)	
Spinal Anesthesia Set with Atraumatic Type (Pencil Point) Spinal Anesthesia Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Hypodermic Needle, Waste Needle Box, Square Plaster)	
Spinal Anesthesia Set with Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Hypodermic Needle, Waste Needle Box, Square Plaster)	
Combined Spinal Epidural Anesthesia Sets	**GMDN: 34845**
Combined Spinal Epidural Anesthesia Set: (Spinal Needle with Combined Application Fixator, Epidural Needle, Epidural Catheter, Epidural LOR Syringe / Automatic LOR Syringe, Epidural Filter, Filtered Aspiration Cannula, Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Catheter Connector(Tuohy Borst Connector), Yellow identification label)	
Single Shot Combined Spinal Epidural Anesthesia Set: (Spinal Needle with Combined Application Fixator, Epidural LOR Syringe / Automatic LOR Syringe, Epidural Needle, Filtered Aspiration Cannula)	
Combined Spinal Epidural Mini Anesthesia Set: (Spinal Needle with Combined Application Fixator, Epidural Needle, Epidural LOR Syringe / Automatic LOR Syringe, Filtered Aspiration Cannula)	
Combined Spinal Epidural Anesthesia Kits	**GMDN: 34845**
Combined Spinal Epidural Anesthesia Kit: (Spinal Needle with Combined Application Fixator, Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Filtered Aspiration Cannula, Hypodermic Needle, 3 ml – 5 ml Inejctor, Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Plaster, Sponge, Waste Needle Box, Yellow Identification Label)	
Epidural Anesthesia Needles – Sets – Kits – Class IIa – Sterile	
Epidural Anesthesia Needles	**GMDN: 58293**
Epidural Anesthesia Sets	**GMDN: 34842**
Epidural Anesthesia Set: (Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Yellow Identification Label)	
Epidural Anesthesia Set (Mini A): (Epidural Needle, Epidural Catheter, Epidural Filter, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Yellow Identification Label)	
Epidural Anesthesia Set (Mini B):	

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(Epidural Catheter, Epidural Filter, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Yellow Identification Label)	
Epidural Anesthesia Set (Mini C): (Epidural Needle, Epidural Catheter, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device)	
Epidural Anesthesia Kits	**GMDN: 34842**
Epidural Anesthesia Kits: (Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Hypodermic Needle, 3 ml – 5 ml Syringe, Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Plaster, Sponge, Waste Needle Box, Yellow Identification Label)	
Echogenic Transforaminal Epidural Cannula with Blunt Tip	**GMDN: 45178**
Echogenic Transforaminal Epidural Cannula with Blunt Tip Sets	**GMDN: 45178**
Echogenic Transforaminal Epidural Cannula with Blunt Tip Set: (Echogenic Transforaminal Epidural Cannula with Blunt Tip Needle, IV Cannula(Branül), 3 ml – 5 ml Syringe, Guide Needle, Filtered Aspiration Cannula, Sponge, Medical Hydrophilic Swab, Hypodermic Needle, Waste Needle Box, Pressure Extension Line, Adhesive Surgical Drape, Sterile Surgical Towel)	
Caudal Anesthesia Needle	**GMDN: 34841**
Caudal Anesthesia Needle – with Filtered Aspiration Cannula	**GMDN: 34841**
Caudal Anesthesia Sets	**GMDN: 34841**
Caudal Anesthesia Set: (Caudal Needle, Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Waste Needle Box, Hypodermic Needle, Square Plaster)	
Intrauterine Contraceptive Device – Class III – Sterile	**GMDN: 46920**
Seldinger (Angiography) Needle – Class III – Sterile	**GMDN: 12747**
Biopsy and Aspiration Needles and Accessories – Class IIa – Sterile	
Manual Guillotine Biopsy Needle	**GMDN: 47540**
Semi-Automatic Guillotine Biopsy Needle	**GMDN: 47540**
Sternal Crista Iliac Aspiration Needle	**GMDN: 35886**
Chiba Needle	**GMDN: 35886**
Amniocentesis Needle	**GMDN: 35886**
Cordocentesis Needle	**GMDN: 35886**
Bone Marrow Biopsy Needle	**GMDN: 46350**
Bone Marrow Biopsy Kit	**GMDN: 46350**
Bone Marrow Biopsy Kit Bone Marrow Biopsy Needle, Marrow Collection Cannula/Probe, Marrow Transfer Ring, Pusher Stylet, 10 ml Syringe, Medical Hydrophilic Swab, Sterile Surgical Towel)	
Medical Accessories / Products for Anesthesia - Class IIa - Sterile	
Guide Needle	GMDN: 45018
Filtered Aspiration Cannula	GMDN: 45316
Epidural Filter	GMDN: 31245
Epidural LOR (Loss Of Resistance) Syringe	GMDN: 18069
Epidural Automatic LOR (Loss Of Resistance) Syringe	GMDN: 18069
Epidural Catheter	GMDN: 35795
Medical Accessories / Products for Anesthesia – Class I – Sterile	
Epidural Catheter Fixing Device	GMDN: 34916
Epidural Filter Fixing Device	GMDN: 37040
Catheter Connector(Tuohy Borst Connector)	GMDN: 46115

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SERTIFIKATAS

Visiška kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42 /EEB PriedasII (išskyrus 4 skirsnį)

M.2016.106.6908-1 Dizaino įvertinimo sertifikatas taikomas III klasės produktams,

nurodytiems šiame sertifikate

Įmonės pavadinimas : TMT Tibbi Medikal Malzemeleri Sanayi ve Ticaret A.S.

Įmonės adresas : Fatih Mah.1188 Sak. Nr. 14 Sarnic Gaziemir, Izmiras/TURKIJA

Susijusi Direktyva ir priedas: : 93/42/EEB medicinos prietaisų direktyva - II priedas, išskyrus 4 skirsnį

Produktai:

1- Spinalinės anestezijos adatos – Rinkiniai – Komplektai – III klasė – Sterilūs
- Spinalinės anestezijos adatos
- Spinalinės anestezijos rinkiniai
- Kombinuoti spinaliniai epidūriniai anestezijos rinkiniai
- Kombinuoti spinaliniai epidūriniai anestezijos komplektai

2- Epidūrinės anestezijos adatos – Rinkiniai – Komplektai – IIa klasė - Sterilūs
- Epidūrinės anestezijos adatos
- Epidūrinės anestezijos rinkiniai
- Epidūrinės anestezijos komplektai
- Echogeninė epidūrinio tarpo adata buku galiuku
- Echogeninės epidūrinio tarpo adatos buku galiuku rinkiniai
- Kaudalinė anestezijos adata
- Kaudalinės anestezijos adatos rinkiniai

3- Intrauterinė kontracepcijos priemonė – III klasė – Sterilios
4- Seldingerio (angiografinė) adata – III klasė – Sterilios
5- Biopsinės ir aspiracinės adatos, jų rinkiniai ir priedai – IIa klasė – sterilūs
6- Medicininiai priedai anestezijai – IIa klasė – Sterilūs
7- Medicininiai priedai anestezijai – I klasė – Sterilūs

Nomenklatūros numeris : 35212, 34845, 58293, 34842, 45178, 34841, 46920, 12747, 47540, 35886, 46350, 45018, 45316, 31245, 18069, 35795, 34916, 37040, 46115
Produktų tipai pridėti

Pažymėjimo numeris Ataskaitos numeris Pradinio vertinimo data	: M.2016.106.6908 : MD.3193.YB : 2016 07 16
Registracijos data	: 2016.07.28
Pakartotinio sertifikavimo įvertinimo data	: 2019.08.01
Pakartotinio išdavimo data/ Nr	: 2020.01.20/01
Galiojimo data	: 2024.05.27

UDEM Tarptautinis
Sertifikavimo Audito
mokymo centras
Pramonė ir prekyba Inc.
Co

Šis dokumentas sudarytas iš dviejų puslapių ir yra priedas prie Sertifikato Nr. M.2016.106.6908, kuris užregistruotas 2016.07.28 ir pakartotinai išduotas 2020.01.20 TMT Tibbi Medikal Malzemeleri Sanayi ve Ticaret A.S. Sertifikatą išdavė UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. Ve Tic. A.S, kuris teikia Notifikuotosios įstaigos paslaugas, identifikacinis Nr. 2292, pagal Medicininių prietaisų direktyvą 93/42/EEB.

Spinalinės anestezijos adatos – Rinkiniai – Komplektai – III klasė – Sterilūs	
Spinalinės anestezijos adatos	**GMDN: 35212**
Quincke tipo spinalinės anestezijos adatos	
Quincke tipo spinalinės anestezijos adatos su pravedėju	
Quincke tipo spinalinės anestezijos adatos su aspiracine kaniule	
Quincke tipo spinalinės anestezijos adatos su pravedėju ir aspiracine kaniule	
Atraumatinės Pencil-point tipo spinalinės anestezijos adatos	
Atraumatinės Pencil-point tipo spinalinės anestezijos adatos su pravedėju	
Atraumatinės Pencil-point tipo spinalinės anestezijos adatos su aspiracine kaniule	
Atraumatinės Pencil-point tipo spinalinės anestezijos adatos su pravedėju ir aspiracine kaniule	
Specialiai lenktos atraumatinės spinalinės anestezijos adatos	
Specialiai lenktos atraumatinės spinalinės anestezijos adatos su pravedėju	
Specialiai lenktos atraumatinės spinalinės anestezijos adatos su aspiracine kaniule	
Specialiai lenktos atraumatinės spinalinės anestezijos adatos su pravedėju ir aspiracine kaniule	
Spinalinės anestezijos rinkiniai	**GMDN: 34845**
Spinalinės anestezijos rinkinys su Quincke tipo spinalinės anestezijos adata	
Spinalinės anestezijos rinkinys su atraumatine Pencil-point tipo spinalinės anestezijos adata	
Spinalinės anestezijos rinkinys su specialiai lenkta atraumatine spinalinės anestezijos adata	
Kombinuoti spinaliniai epidūriniai anestezijos rinkiniai	**GMDN: 34845**
Kombinuotas spinalininis epidūrinis anestezijos rinkinys	
Vieno žingsnio kombinuotas spinalininis epidūrinis anestezijos rinkinys	
Kombinuotas spinalininis epidūrinis MINI anestezijos rinkinys	
Kombinuoti spinaliniai epidūriniai anestezijos komplektai	**GMDN: 34845**
Kombinuotas spinalinis epidūrinis anestezijos komplektas	
Epidūrinės anestezijos adatos – Rinkiniai – Komplektai – IIa klasė - Sterilūs	
Epidūrinės anestezijos adatos	**GMDN: 58293**
Epidūrinės anestezijos rinkiniai	**GMDN: 34842**
Epidūrinės anestezijos rinkinys	
Epidūrinės anestezijos rinkinys (MINI A)	
Epidūrinės anestezijos rinkinys (MINI B)	
Epidūrinės anestezijos rinkinys (MINI C)	
Epidūrinės anestezijos komplektai	**GMDN: 34842**
Epidūrinės anestezijos komplektas	
Echogeninė epidūrinio tarpo adata buku galiuku	**GMDN: 45178**
Echogeninės epidūrinio tarpo adatos buku galiuku rinkiniai	**GMDN: 45178**
Echogeninės epidūrinio tarpo adatos buku galiuku rinkinys	
Kaudalinė anestezijos adata	**GMDN: 34841**
Kaudalinė anestezijos adata su aspiracine kaniule	**GMDN: 34841**
Kaudalinės anestezijos adatos rinkiniai	**GMDN: 34841**
Kaudalinės anestezijos adatos rinkinys	
Intrauterinė kontracepcijos priemonė – III klasė – Sterilios	**GMDN: 46920**
Seldingerio (angiografinė) adata – III klasė – Sterilios	**GMDN: 12747**
Biopsinės ir aspiracinės adatos, jų rinkiniai ir priedai – IIa klasė – sterilūs	

Rankinė giljotinos biopsinė adata	**GMDN: 47540**
Pusiau atomatinė giljotinos biopsinė adata	**GMDN: 47540**
Sternalinė aspiracinė adata	**GMDN: 35886**
Chiba adata	**GMDN: 35886**
Amniocentezės adata	**GMDN: 35886**
Kordocentezės adata	**GMDN: 35886**
Kaulų čiulpų biopsinė adata	**GMDN: 46350**
Kaulų čiulpų biopsijos komplektas	**GMDN: 46350**
Kaulų čiulpų biopsijos komplektas	
Medicininiai priedai anestezijai – IIa klasė – Sterilūs	
Kreipiamoji adata	**GMDN: 45018**
Aspiracinė kaniulė	**GMDN: 45316**
Epidūrinis filtras	**GMDN: 31245**
Epidūrinis LOR švirkštas	**GMDN: 18069**
Epidūrinis automatinis LOR švirkštas	**GMDN: 18069**
Epidūrinis kateteris	**GMDN: 35795**
Medicininiai priedai anestezijai – I klasė – Sterilūs	
Epidūrinio kateterio fiksavimo priemonės	**GMDN: 34916**
Epidūrinio filtro fiksavimo priemonės	**GMDN: 37040**
Tuohy Borst konektorius	**GMDN: 46115**

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Co

MDD UZATMA ONAY YAZISI

05/12/2023

İlgili Makama,

93/42/EEC Tıbbi Cihaz Yönetmeliği kapsamında onaylanmış kuruluş olarak faaliyet gösteren UDEM A.Ş. olarak Tablo-1'de bilgileri verilen firma ve ürünler için 93/42/EEC Tıbbi Cihaz Yönetmeliği kapsamında 20/01/2020 tarihinde EC sertifikası düzenlediğimizi ve ilgili sertifikanın bitiş tarihi öncesi Tablo 1'de verilen ürünleri için sertifikanın geçerli olduğunu beyan ederiz.

Tablo-1

Firma Adı	EC Sertifika No	Kapsam	Geçerlilik Tarihi
TMT TIBBİ MEDİKAL MALZ. SAN. VE TİC. A.Ş.	M.2016.106.6908 M.2016.106.6908-1	– SPİNAL ANESTEZİ İĞNELERİ-SETLERİ- KİTLERİ – EPİDURAL ANESTEZİ İĞNELERİ- SETLERİ- KİTLERİ – SELDİNGER (ANJİYOGRAFİ) İĞNE – BİYOPSİ VE ASPİRASYON İĞNELERİ-KİTLERİ VE AKSESUARLARI – ANESTEZİ İÇİN TIBBİ AKSESUARLAR	27.05.2024

2 Nisan 2023 tarihli ve 32151 sayılı Resmi Gazete'de yayımlanan Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmeliği kapsamında 93/42/EEC sertifikalarının geçerlilik sürelerinin uzatılmasına yönelik belirtilen hükümlerin uygulanabilirliğini teyit etmek amacıyla ilgili firmadan UDFRM.305 9342EEC Kapsamında Geçerli EC Sertifikaları İle İlgili Uzatma Süreci Bilgi Formu sağlanmıştır. Firmanın sağladığı bilgiler incelendiğinde söz konusu EC sertifikası kapsamındaki Tablo-2'de verilen ürünler ve / veya yerini alması amaçlanan cihazlar için (AB) 2017/745 kapsamında yetkilendirilmiş başka bir onaylanmış kuruluşa başvuru yapıldığı ve/veya ilgili onaylanmış kuruluş ile sözleşme imzalandığı bilgisi paylaşılmıştır.

Tablo-2

Cihaz	MDR OK	Başvuru Tarihi	Sözleşme Tarihi
– SPİNAL ANESTEZİ İĞNELERİ-SETLERİ-KİTLERİ	2696	27.12.2021	30.12.2021
– EPİDURAL ANESTEZİ İĞNELERİ-SETLERİ- KİTLERİ – SELDİNGER (ANJİYOGRAFİ) İĞNE – BİYOPSİ VE ASPİRASYON İĞNELERİ-KİTLERİ VE AKSESUARLARI	2696	15.05.2022	07.09.2022

Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmeliği uyarınca yukarıda belirtilen firma için EC sertifikası kapsamında yer alan ve aynı zamanda MDR başvurusu olan ürünlerine yönelik, MDR sözleşmesi sonrası diğer onaylanmış kuruluş tarafından üstlenilmediği sürece, ilgili Yönetmeliğin Md. 120 (3e) bendinde belirtildiği şekilde gözetim denetim sorumluluğunu 30/11/2023 tarihinde ilgili firma ve UDEM A.Ş. tarafından imzalanan UDFRM.07-2 EC Sertifikalarının Geçerlilik Sürelerinin

MDD UZATMA ONAY YAZISI

Uzatılmasına İlişkin Ek Sözleşme ile 26 Eylül 2024 tarihine kadar üstlendiğimizi beyan ederiz. EC sertifikası kapsamında yer alıp MDR başvurusu/sözleşmesi bulunmayan ürünler için 26.05.2024 tarihi itibariyle herhangi bir gözetim sorumluluğumuz bulunmamaktadır.

Söz konusu gözetimlerin gerçekleştirilmesi firmanın ilgili Yönetmeliğin Md. 120 (3c) kapsamında belirtilen yükümlülükleri karşılamasına bağlı olarak sürdürülecektir.

Serian DOMA

Tıbbi Ci me Sorumlusu

İŞİ BELGELENDİR...

SAN. VE TİC. A.Ş

lukent Mah. 2073. Sk. No:10 Ümitköy - Çankaya / ANKAR

(0.312) 443 03 90 (pbx) Fax: (0.312) 443 03 7

ANBEY Vergi Dairesi : 885 044 2

MDD EXTENSION APPROVAL LETTER

05/12/2023

To whom It May Concern,

As UDEM A.Ş., operating as a notified body within the scope of the 93/42/EEC Medical Device Regulation, we have issued an EC certificate on the date 20/01/2020 within the scope of the 93/42/EEC Medical Device Directive for the company and products whose information is given in Table-1. We declare that the certificate is valid for the products given in Table-1 before the expiry date of the relevant certificate.

Table-1

Company Name	EC Certificate No	Scope	Expiry Date
TMT TIBBİ MEDİKAL MALZ. SAN. VE TİC. A.Ş.	M.2016.106.6908 M.2016.106.6908-1	-SPINAL ANESTHESIA NEEDLES – SETS – KITS -EPIDURAL ANESTHESIA NEEDLES – SETS – KITS -SELDINGER (ANGIOGRAPHY) NEEDLE -BIOPSY AND ASPIRATION NEEDLES AND ACCESSORIES-STERILE -MEDICAL ACCESSORIES FOR INFUSION-STERILE	27.05.2024

In order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates within the scope of the Regulation on the Amendment of the Medical Device Regulation published in the Official Gazette dated 02 April 2023 and numbered 32151, UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 9342EEC has been provided from the relevant company. When the information provided by the company is reviewed, it has been shared that an application has been made to another notified body authorized under (EU) 2017/745 for the products given in Table-2 within the scope of the said EC certificate and/or the devices intended to replace it and/or a contract has been signed with the relevant notified body.

Table-2

Device	MDR NB	Date of Application	Date of Contract
SPINAL ANESTHESIA NEEDLES – SETS – KITS	2696	27.12.2021	30.12.2021
-EPIDURAL ANESTHESIA NEEDLES – SETS – KITS -SELDINGER (ANGIOGRAPHY) NEEDLE -BIOPSY AND ASPIRATION NEEDLES AND ACCESSORIES-STERILE	2696	15.05.2022	07.09.2022

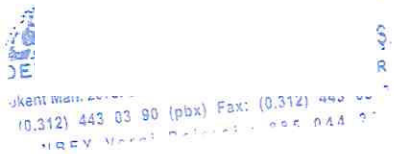
In accordance with the Regulation Amending the Medical Device Regulation, for the products listed in Table-2, which are within the scope of the EC certificate for the above-mentioned company and are also under the MDR contract, unless undertaken by the other notified body after the MDR

contract, we declare that we have undertaken the surveillance audit responsibility until 26 September 2024 with UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates signed by the relevant company and UDEM A.Ş. on 30/11/2023 as specified in Article 120 (3e) of the relevant Regulation. As of 26.05.2024, we do not have any surveillance responsibility for products that are within the scope of EC certificate but do not have an MDR application/contract.

The execution of the said surveillance audits will continue depending on the company's fulfillment of the obligations set forth in Article 120 (3c) of the relevant Regulation.

Serian DOMA

Medical Devic [redacted] nsible



MEDICAL EQUIPMENT PRODUCER
Katarzyna Meger
Łęczycka 65
85-737 Bydgoszcz
VAT-ID PL5541660503
tel./fax (52) 3420399, 3426688

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)

Wytwórnia Sprzętu Medycznego GALMED Katarzyna Meger

Łęczycka 65, 85-737 Bydgoszcz, Poland

Notified body name	TÜV NORD Polska Sp. z o.o.
Notified body number	2274
Directive Certificate number(s) to which this confirmation is made (if applicable)	TNP/MDD/0395/2032/2021 TNP/MDD/0396/2032/2021 TNP/MDD/0397/2032/2021
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	24.05.2024
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and

- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificates** as listed above covering the devices listed in Enclosure 1 were issued after 25 May 2017, and were valid on 26 May 2021 and have not been withdrawn afterwards.

A derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority, as the Certificates expire after 20 March 2023 and

formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024 (we are awaiting the acceptance of submitted application and offer for recetrification which acceptance is followed by agreement to be signed by both parties).

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place. The recertification is planned on 9-11 of July. The delay is caused by lack of free dates before current certificate expiration.

➢ **Devices as listed in the attached schedule**

- continue to comply with the MDD,
- have no significant changes implemented in the design and intended purpose,
- do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Wytwórnia Sprzętu Medycznego GALMED Katarzyna Meger

Bydgoszcz, 21.05.2024

meger@galmed.com.pl
qms@galmed.com.pl

Enclosure 1 - Schedule of Devices

Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Identification of the devices	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificates prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Suction catheters for upper respiratory tract	TNP/MDD/0395/2032/2021	24.05.2024	TÜV NORD Polska Sp. z o.o. no 2274	TÜV NORD Polska Sp. z o.o. no 2274	31.12.2028
Urological catheters					
Rectal catheters					
Rectal tubes					
Feeding catheters					
Stomach tubes					
Duodenal tubes					
Thorax catheters with X-ray contrast					
Wound drains					
Suction sets for operative field					
Sets for transfusion					
Infusion pumps sets					
Oxygen catheters					
Extension tubes for oxygen					
Bags for laparoscopy for tissue samples					
Jo-Lo Covers for surgical instruments					

Hydrophilic coated urological catheters Meatal dilators	TNP/MDD/0396/2032/2021	24.05.2024	TÜV NORD Polska Sp. z o.o. no 2274	TÜV NORD Polska Sp. z o.o. no 2274	31.12.2028
Catheter plugs Connectors for tubes and catheters Drains Suction tubes Active drainage sets Urinal bags for infants	TNP/MDD/0397/2032/2021	24.05.2024	TÜV NORD Polska Sp. z o.o. no 2274	TÜV NORD Polska Sp. z o.o. no 2274	31.12.2028

CERTYFIKAT WE / EC CERTIFICATE

zgodny z 93/42/EWG Załącznik II(b.p. 4) / *acc. 93/42/EEC Annex II(w.o. 4)*

Niniejszym zaświadcza się, że firma / *This certifies, that the company*

Galmed Wytwórnia Sprzętu Medycznego Katarzyna Meger
ul. Łęczycka 65, PL / 85-737 Bydgoszcz

dla kategorii wyrobów sterylnych klasy IIa / *for the product category class IIa in sterile condition*
(Lista wyrobów patrz załącznik 1 / *List of products see annex 1*)

Sterylne wyroby medyczne jednorazowego użytku z tworzyw sztucznych i metalu.

Sterile disposable medical devices made of plastic and metal.

stosuje system zapewnienia jakości w projektowaniu, produkcji i kontroli końcowej wymienionych wyrobów zgodny z wymaganiami Załącznika II (z wyłączeniem sekcji 4) dyrektywy 93/42/EWG. Dodatkowo, przy znaku CE musi zostać naniesiony numer identyfikacyjny jednostki notyfikowanej. Ważność tego certyfikatu zależna jest od utrzymania systemu zapewnienia jakości zgodnego z wymaganiami dyrektywy i jego nadzorowania przez jednostkę notyfikowaną zgodnie z Załącznikiem II, rozdział 5. Certyfikat nie może być przenoszony pod żadnym warunkiem.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (excluding section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Nr rej. / *Reg.-No.* TNP/MDD/0395/2032/2021

Raport nr / *Report No.*: PL2032/2021

Ważny od / *Valid from* **25-05-2021**

Ważny do / *Valid until* **24-05-2024**

Jolwita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 25-05-2021

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29 40-085 Katowice

☎ +48 32 786 46 46, Fax +48 32 786 46 01
www.tuv-nord.pl, biuro@tuv-nord.pl

ZAŁĄCZNIK nr 1, strona 1 z 2 / ANNEX *No. 1, page 1 of 2*

do certyfikatu numer rejestracyjny / *to Certificate Registration No.:* **TNP/MDD/0395/2032/2021**

Raport nr / *Report No.*: PL2032/2021

Ważny od / *Valid from* **25-05-2021**

Ważny do / *Valid until* **24-05-2024**

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Cewniki do odsysania górnych dróg oddechowych / *Suction catheters for upper respiratory tract*	Cewnik do odsysania górnych dróg oddechowych typ A z otworem centralnym / *Suction catheter for upper respiratory tract type A with central opening*	IIa	10749
	Cewnik do odsysania górnych dróg oddechowych typ B z dwoma otworami / *Suction catheter for upper respiratory tract type B with central opening and lateral eye*		
	Cewnik do odsysania górnych dróg oddechowych typ C z otworem centralnym i dwoma bocznymi / *Suction catheter for upper respiratory tract type C with central opening and two lateral eyes*		
	Cewnik do odsysania górnych dróg oddechowych do lewego drzewa oskrzelowego (zgięty) / *Suction catheter for upper respiratory tract for left bronchius (angled)*		
Cewniki urologiczne / *Urological catheters*	Cewnik urologiczny Nelaton / *Urological catheter* Nelaton	IIa	10764
	Cewnik urologiczny Nelaton kobiecy / *Urological catheter female Nelaton*		
	Cewnik urologiczny Tiemann / *Urological catheter Tiemann*		
	Cewnik urologiczny Couvelaire / *Urological catheter Couvelaire*		
Cewniki rektalne / *Rectal catheters*	Cewnik rektalny / *Rectal catheter*	IIa	10746
Kanki doodbytnicze / *Rectal tubes*	Kanka doodbytnicza / *Rectal tube*	IIa	14227
Cewniki do karmienia / *Feeding tubes*	Cewnik do karmienia / *Feeding tube*	IIa	14199
Zgłębniki żołądkowe / *Stomach tubes*	Zgłębnik żołądkowy / *Stomach tube*	IIa	14221
	Zgłębnik żołądkowy Salem / *Salem stomach tube*		
	Zgłębnik żołądkowy Gastric LightGuide / *Stomach tube Gastric LightGuide*		
Zgłębniki dwunastnicze / *Duodenal tubes*	Zgłębnik dwunastniczy / *Duodenal tube*	IIa	14202
Cewniki Thorax z kontrastem Rtg / *Thorax catheters with X-ray contrast*	Cewnik Thorax z kontrastem Rtg / *Thorax catheter with X-ray contrast*	IIa	11308
	Cewnik Thorax z kontrastem Rtg zgięty / *Thorax catheter with X-ray contrast angled*	IIa	
	Cewnik Thorax z kontrastem Rtg Cardio / *Thorax catheter with X-ray contrast Cardio*	IIa	
	Cewnik Thorax z kontrastem Rtg z trokarem / *Thorax catheter with X-ray contrast with trocar*	IIa	
Dreny do ran / *Wound drains*	Dren do ran typu Redon / *Wound drain type Redon*	IIa	11305
	Dren do ran typu Redon z trokarem / *Wound drain type Redon with trocar*		
	Dren do ran typu Ulmer / *Wound drain type Ulmer*		
	Dren do ran typu Ulmer z trokarem / *Wound drain type Ulmer with trocar*		
	Dren brzuszny / *Abdominal drain*		

Katowice, 25-05-2021

ijąca Wyroby Medyczne /
Certification body for medical devices

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

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ZAŁĄCZNIK nr 1, strona 2 z 2 / ANNEX *No. 1, page 2 of 2*

do certyfikatu numer rejestracyjny / *to Certificate Registration No.:* **TNP/MDD/0395/2032/2021**

Raport nr / *Report No.*: PL2032/2021

Ważny od / *Valid from* **25-05-2021**

Ważny do / *Valid until* **24-05-2024**

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Zestawy do pola operacyjnego / Suction sets for operative field	Końcówka do odsysania pola operacyjnego / *Suction handle for operative field*	IIa	16883
	Końcówka do odsysania pola operacyjnego z przewodem ssącym / *Suction handle for operative field with suction tube*		
	Końcówka do odsysania pola operacyjnego z rączką Gal-Flex / *Gal-Flex Suction Handle for operative field*		
	Końcówka do odsysania pola operacyjnego z rączką Gal-Flex z przewodem ssącym / *Gal-Flex Suction handle for operative field with suction tube*		
	Rączka Gal-Flex / *Gal-Flex handle*		
	Przewód ssący do końcówek do pola operacyjnego / *Suction tube for suction handles for operative field*		16779
Przyrządy do przetaczania / *Sets for transfusion*	Przyrząd do szybkiego przetaczania krwi / *Set for quick blood transfusion*	IIa	10421
	Przyrząd do przetaczania krwi /*Set for blood transfusion*		
Zestawy do pompy infuzyjnej / *Infusion pump sets*	Zestaw do pompy infuzyjnej / *Infusion pump set*	IIa	16579
Cewniki do podawania tlenu przez nos / *Oxygen catheters*	Cewnik do podawania tlenu przez nos / *Oxygen cannula*	IIa	12700
	Cewnik pojedynczy do podawania tlenu przez nos – perforowany / *Oxygen catheter - perforated*	IIa	12702
	Cewnik pojedynczy do podawania tlenu przez nos - z kołnierzem z gąbki / *Oxygen catheter - with foam collar*	IIa	12702
Przedłużacze do tlenu / *Extension tubes for oxygen*	Przedłużacze do tlenu / *Extension tubes for oxygen*	IIa	12875
Worki do laparoskopii do preparatów tkankowych / *Bags for laparoscopy for tissue samples*	Worek do laparoskopii do preparatów tkankowych GAL-Bag / *Bag for laparoscopy for tissue samples GAL-Bag*	IIa	13655
Ochraniacze na instrumenty chirurgiczne Jo-Lo / *Jo-Lo Covers for surgical instruments*	Ochraniacz na instrumenty chirurgiczne Jo-Lo ochraniacz na haki / *Jo-Lo Cover for surgical instruments cover for hooks*	IIa	15571
	Ochraniacz na instrumenty chirurgiczne Jo-Lo ochraniacz na szczypce / *Jo-Lo Cover for surgical instruments cover for forceps*	IIa	
Zestawy do pozyskiwania osocza bogatopłytkowego / *Sets for harvesting, preparing and applying autologous concentrated platelet-rich plasma A-PRP*	Zestaw do pozyskiwania osocza bogatopłytkowego A-PRP Novareg Nowoczesna Regeneracja / *NOVAREG - Modern Recovery Set for Harvesting, Preparing and Applying Autologous Concentrated Platelet-Rich Plasma A-PRP.*	IIa	16811
Korki iniekcyjne Luer lock żeńskie / *Injection caps luer lock female*	Korek iniekcyjny Luer lock żeński / *Injection cap luer lock female*	IIa	11729
Uniport / *Uniport*	Uniport / *Uniport*	IIa	20395

Katowice, 25-05-2021

roby Medyczne /
al devices

Jednostka notyfikowana Numer identyfikacyjny 2274
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CE SERTIFIKATAS

dėl sterilizacijos aspekto

pagal 93/42 / EEC II priedą (b.p. 4) / ÂCC • Ö3 / 42 / EEC priedas kaip.o. 4m
Patvirtina, kad įmonė

Galmed medicinos įrangos gamykla Katažina Meger
Łęczycka ul. 65, PL / 85-737 Bydgoszcz

Produktų kategorijai IIa sterilūs
Gaminių sąrašą žr. 1 priede

Sterilūs vienkartiniai medicininiai gaminiai iš plastiko ir metalo

Įdiegė kokybės sistemą kūrimui, gamybai ir galutinei apžiūrai, remiantis 93/42/EEC direktyvos II Priedo reikalavimais (išskyrus 4 skyrių). CE žymėjimui reikalingas papildomas notifikuotos įstaigos notifikavimo numeris. Sertifikato galiojimas paremtas kokybės valdymo sistemos priežiūra atliekama remiantis direktyvos reikalavimais ir jo stebėsena (atliekama notifikuotos įstaigos, pagal II Priedo skyrių 5). Šis sertifikatas negali būti perduodamas jokiomis sąlygomis.

Registracijos Nr. TNP/MDD/0396/2032/2021
Ataskaitos Nr.: PL2032/2021

Galioja nuo: **2021-05-25**
Galioja iki: **2024-05-24**

Jowita Juzwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katovicai, 2021-05-21

Notifikuojančios institucijos identifikavimo Nr. 2274

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PRIEDAS Nr. 1,puslapis 1 iš 1

Registracijos Nr.: TNP/MDD/0396/2032/2021

Ataskaitos Nr.: PL2032/2021

Galioja nuo 2021-05-25

Galioja iki 2024-05-24

Tipas	Produktai	Klasė	UMDNS
Atsiurbimo kateteriai viršutiniams kvėpavimo takams	Atsiurbimo kateteriai su A tipo centrine anga	IIa	10749
	Atsiurbimo kateteriai su B tipo centrine anga ir šonine skyle		
	Atsiurbimo kateteriai su C tipo centrine anga ir 2 šoninėm skylėm		
	Atsiurbimo kateteriai kairiajam bronchui lenkti		
Urologiniai kateteriai	Nelaton kateteriai	IIa	10764
	Moteriški Nelaton kateteriai		
	Tieman kateteriai		
	Couvelaire tipo kateteriai		
Rektaliniai kateteriai	Rektaliniai karteteriai	IIa	10746
Rektaliniai zondai	Rektaliniai zondai	IIa	14227
Maitinimo zondai	Maitinimo zondai	IIa	14199
Skrandžio zondai	Skrandžio zondai	IIa	14221
	Salem tipo skrandžio zondai		
	Skrandžio zondai Gastric LightGuide		
Duodenaliniai zondai	Duodenaliniai zondai	IIa	14202
Torakaliniai kateteriai rengeno kontrastiniai	Torakaliniai kateteriai rentgeno kontrastiniai	IIa	11308
	Torakaliniai kateteriai rentgeno kontrastiniai lenkti	IIa	
	Torakaliniai kateteriai rentgeno kontrastiniai Cardio	IIa	
	Torakaliniai kateteriai rentgeno kontrastiniai su trokaru	IIa	
Redon drenai	Redon drenai	IIa	11305
	Redon drenai su trokaru		
	Ulmer tipo žaizdų drenai		
	Ulmer tipo žaizdų drenai su trokaru		
	Pilvo drenai		

Katovicai, 2021-05-21

Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Notifikuojančios institucijos identifikavimo Nr. 2274

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POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 29.04.2024

KW/MC/2024/0168

Manufacturer Name:

Hagmed sp. z o.o. Sp. k.

Adress:

Tomaszowska 32,
96-200 Rawa Mazowiecka
Poland

Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Polish Centre for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1434 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Hagmed sp. z o.o. sp. k.
Tomaszowska 32
96-200 Rawa Mazowiecka
Poland

SRN Number: PL-MF-000021862

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement

concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Tomasz Koeber

Head of Medical Device Certification Department

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ablation electrodes EA	Class III	Not applicable	1434-MDD-576/2019 1434-MDD-577/2019
Temporary transvenous pacing electrodes ES	Class III	Not applicable	1434-MDD-050/2019 1434-MDD-051/2019
Electrophysilogy diagnostic electrodes steerable EES and non-steerable EE	Class III	Not applicable	1434-MDD-048/2019 1434-MDD-049/2019
Resectoscope electrodes	Class IIb	Not applicable	1434-MDD-052/2019
Etension cables of electrophysiological electrodes	Class Is	Not applicable	1434-MDD-050/2020
Applicators for collecting genetic material	Class Is	Applicators for specimen collecting; Sterile cotton swabs	1434-MDD-056/2019 1434-MDD-055/2019
Embolectomy catheters	Class IIa	Not applicable	1434-MDD-053/2019

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	Not applicable	Not applicable	Not applicable

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
15.04.2024	KW/MC/2024/0152	Initial issue
24.04.2024	KW/MC/2024/0168	Addition of Embolectomy catheters to the Table 1

CERTIFICATE

EC No. 1434-MDD-053/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

HAGMED Spółka z o.o.
Spółka Komandytowa
32 Tomaszowska Str. 96-200 Rawa Mazowiecka Poland

for the design, manufacture and final inspection of
medical devices, class IIa

Embolectomy catheters

The list of medical devices covered by this certificate is given in the Annex No. 1

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2019-04-15 to 2024-04-14

The date of issue of the Certificate: 2019-04-15

CE 1434

Application No.: 099/2018
Module H

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

Certificate No. **1434-MDD-053/2019**
Issued under the contract no. **MD-40/2018**
Bears the PCBC hologram
Warsaw, 15.04.2019

CE SERTIFIKATAS
EC Nr. 1434-MDD-053/2019
Pilnai įdiegta kokybės užtikrinimo sistema

Pagal 93/42/EEC medicinos prietaisų direktyvą

Lenkijos testavimo ir sertifikavimo centras patvirtina, kad įmonė
taiko kokybės užtikrinimo sistemą:

HAGMED Spolka z o.o.
Spolka Komandytowa
32 Tomaszowska Str.
96-200 Rawa Mazowiecka
Lenkija

projektuojant, gaminant ir galutinai tikrinant medicinos prietaisus, IIa klasė

Embolektominiai kateteriai

Medicininių priemonių sąrašas pagal šį sertifikatą yra pateiktas priede Nr. 1

atitinka II priedo reikalavimus (išskyrus 4 skyrių)
pagal direktyvą 93/42/EEC (su pakeitimais)
vykdant pagal Lenkijos įstatymus,
tai patvirtina atliktas PCBC auditas

Šis sertifikatas galioja: nuo 2019.04.15 iki 2024.04.14
Sertifikato išdavimo data: 2019.04.15

Taikymo Nr.: 099/2018
Modulis H

parašas
mgr Anna Wyroba
Viceprezidentė

Lenkijos testavimo ir sertifikavimo centras 23A Klobucka g., 02-699 Varšuva, Lenkija, tel. nr. +48 22 46 45 200, el. paštas: pcbc@pcbc.gov.pl

Sertifikato Nr. 1434-MDD-053/2019
Išleista pagal sutarties nr. MD-04/2018
PCBC hologramа
Varšuva, 2019.04.15

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11168-2017-CE-IND-NA-PS Rev 1.0	PRJC-503753-2014-MSL-IND	27 May 2024

This is to certify that the quality system of:

Harsoria Healthcare Pvt. Ltd.

110-111, UDYOG VIHAR PHASE-4, GURUGRAM-122015, HARYANA, INDIA

For design, production and final product inspection/testing of:
STERILE MEDICAL DEVICES FOR INFUSION AND TRANSFUSION THERAPY

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 14 July 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

The certificateis digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om MedisinskUtstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 5262-2014-CE-IND-NA 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-12
1.0	**Recertification**	2020-07-14

Products covered by this Certificate:

Product Description	Product Name	Class
Intravascular Catheter / IV Catheter / IV Cannula	Sizes 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Safety IV Cannula/ Safety IV Catheter	Sizes 14G, 16G, 17G, 18G, 20G, 22G, 24G	IIa
Arterial Venous Fistula Needle Set	Sizes: 14G, 15G, 16G, 17G, 18G	IIa
Three Way Stopcock/3-Way Stopcock with Extension Tube	Tube Length 5 cm - 300 cm	IIa
Extension Tube/ Extension Tubing Set	Tube Length 5 cm - 300 cm	IIa
IV Flow Regulator / Flow Regulator / Flow Regulator Set		IIa
Injection Stopper / Heparin Lock		IIa
Combi Luer Lock		IIa
Luer Cap / Threaded Stopper		IIa

The complete list of devices is filed with the Notified Body

Certificate No.:
11168-2017-CE-IND-NA-PS Rev 1.0

Project No.:
PRJC-503753-2014-MSL-IND

Valid Until:
27 May 2024

Sites covered by this certificate

Site Name	Address
Harsoria Healthcare Pvt. Ltd.	110-111, UDYOG VIHAR PHASE-4, GURUGRAM-122015, HARYANA, INDIA

EU Representative
mdi Europa GmbH
Langenhagener Str. 71
D-30855 Langenhagen, GERMANY
Email: info@mdi-europa.com

Certificate No.:	Project No.:	Valid Until:
11168-2017-CE-IND-NA-PS Rev 1.0	PRJC-503753-2014-MSL-IND	27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate