SZUTEST
Konformitätsbewertungsstelle GmbH

INFORMATIVE LETTER FOR A FORMAL APPLICATION

To whom it may concern,

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** on NANDO, received a formal application before 26.05.2024 in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the following manufacturer.

Company Name	DLR MEDİKAL SAN.ve DIŞ TİC.LTD.ŞTİ.
Address	İSTANBUL DERİ ORGANİZE SANAYİ BÖLGESİ DİLEK SOKAK NO:2/A TUZLA /İSTANBUL/TURKEY
SRN Number (if available)	TR-MF-000024447
Formal Application Date:	13.05.2024

SZUTEST Konformitätsbewertungsstelle GmbH will evaluate the logged formal application and in case of a positive result will sign a written agreement in accordance with Section 4,3 second subparagraph of Annex VII of MDR until 26.09.2024. Once a written agreement is signed **"Notified Body Confirmation Letter"** will be issued by SZUTEST Konformitätsbewertungsstelle GmbH to **replace** this letter. In any case, this letter will expire on **26.09.2024.**

The devices covered by this letter are presented in below Table 1. The scope of this letter and the "Notified Body Confirmation Letter" may differ from each other. In such case, the scope presented in the "Notified Body Confirmation Letter" shall be considered.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

Hasan AKKÖK
Competent Authority and Committee Coordinator

SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975
Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMANY

SZUTEST
Konformitätsbewertungsstelle GmbH

Table 1: Devices that SZUTEST Konformitätsbewertungsstelle GmbH has received a formal application.

Device name or Basic UDI-DI (Under MDR application)	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Long-Term Hemodialysis Catheter and Set	Certificate #1; M.2016.106.7244 Issue Date: 07.12.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.
Short-Term Hemodialysis Catheter and Set	Certificate #1; M.2016.106.7244 Issue Date: 07.12.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.
Ureteral Stents	Certificate #1; M.2016.106.6518 Issue Date: 29.03.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.

Date	Action
2024/05/23	Initial issue

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

NOTIFIED BODY CONFIRMATION LETTER
No: MD0114-CL-01

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 Regulation (EU) 2017/745 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain medical devices.

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** 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:

Company Name	DLR MEDİKAL SAN.ve DIŞ TİC.LTD.ŞTİ.
Address	Şerifali Mah. Beyan Sok. No:36/A Ümraniye İSTANBUL / TÜRKİYE
SRN Number (if available)	TR-MF-000024447

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 SZUTEST Konformitätsbewertungsstelle GmbH 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 SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under 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 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 with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 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
- 31 December 2028 for Annex XVI products which do not require a clinical investigation.
- 31 December 2029 for Annex XVI products which require a clinical investigation.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET IŞIKLAR
General Manager

SZUTEST
Friedrich-Ebert-Anlage 36
60325 Frankfurt am Main
USt-IdNr. DE815819575
info@szutest-germany.de

SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975
Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMANY

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	*N/A*	*N/A*	*N/A*

Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Long-Term Hemodialysis Catheter and Set	Class III	Same	Certificate #1; M.2016.106.7244 Issue Date: 07.12.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.
Short-Term Hemodialysis Catheter and Set	Class III	Same	Certificate #1; M.2016.106.7244 Issue Date: 07.12.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. Certificate #2; M.2016.106.7244-1 Issue Date: 07.12.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.
Ureteral Stents	Class IIb	Same	Certificate #1; M.2016.106.6518 Issue Date: 29.03.2016 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/09/24	MD0114-CL-01	Initial issue

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de