Digitally signed by Capanji Andrei
Date: 2022.04.14 22:37:38 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

Full Quality Assurance System

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

M.2016.106.7244-1 Desingn Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

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	: - Sterile Central Venous Catheter, Kits and Accessories - Class III - Sterile Long Term Haemodialysis Catheter, Kits and Accessories - Class III - Sterile Short Term Haemodialysis Catheter, Kits and Accessories - Class IIa - Sterile Polypropylene Surgical Mesh - Class IIb
GMDN	: 10729, 37278, 46979, 16048

Product Types are attached.

Certificate Number	: M.2016.106.7244
Report Number	: MD.3098.YB
Initial Assessment Date	: 22.07.2016
Registration Date	: 07.12.2016
Recertification Assessment Date	: 24.10.2019
Reissue Date / No	: 27.04.2020/01
Revision Date /No	: 08.05.2020/01
Expiry Date	: 27.05.2024

UDEM International Certification 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 revision number 01, with the number M.2016.106.7244 and with the registration date of 07.12.2016 and with the revision date of 08.05.2020 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. Central Venous Catheter (GMDN:10729)

Lumens	Size	Length
Single Lumen	02Fr – 08Fr	05cm – 60cm
Dual Lumen	03Fr – 08Fr	05cm – 60cm
Triple Lumen	04Fr – 8,5Fr	08cm – 60cm
Quatra Lumen	05Fr – 08Fr	08cm – 30cm
Penta Lumen	02Fr – 08Fr	15cm – 30cm

1.1 Central Venous Catheter Kit Accessories

Injection Cap
Introducer Needle
Y Needle
Syringe (5cc – 10cc)
Guide Wire
Dilator
Scalpel
Y Connector
End Cap
EKG Cable
Fixation Wing
Touhy Borst Adaptor
Catheter Fixation Band
Unifix
Suture
Sterile Cover
Patient ID card

2. Long Term Haemodialysis Catheter (GMDN:37278)

Lumens	Size	Length
Dual Lumen	12Fr – 16Fr	19cm – 55cm

2.1 Long Term Haemodialysis Catheter Kit Accessories

Injection Cap
Introducer Needle
Y Needle
Syringe (5cc – 10cc)
Guide Wire
Dilator
Scalpel
Y Connector
Peel Away Sheath
Tunneler
Stylet
Fixation Wings

UDEM APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

Unifix
Catheter Fixation Band
Clamp
Repair Kit
Suture
Sterile Cover
Patient ID card

3. Short Term Haemodialysis Catheter (GMDN:46979)

Lumens	Size	Length
Dual Lumen	6,5Fr – 14Fr	10cm – 35cm
Triple Lumen	08Fr – 14Fr	10cm – 20cm

3.1 Short Term Haemodialysis Catheter Kit Accessories

Injection Cap
Introducer Needle
Y Needle
Syringe(5cc – 10cc)
Guide Wire
Dilator
Scalpel
Y Connector
Fixation Wings
Catheter Fixation Band
Unifix
Clamp
Suture
Sterile Cover
Patient ID card

4. Polypropylene Surgical Meshes(GMDN:16048)

Rectangular Meshes
Oval Meshes
Round Meshes
Hernia Meshes

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.