



# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : DLR Medikal San. ve Diş Tic. Ltd. Şti.  
Company Address : Şerifali Mah. Beyan Sok. No:36/A Ümraniye İSTANBUL / 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

  
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](http://www.udem.com.tr).

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<b>1. Guide Wire - Class IIa</b>	<b>GMDN</b>	<b>9.TURP Loops - Class IIb</b>	<b>GMDN</b>
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
<b>2. Drainage (PCN) Catheter and Set - Class IIa</b>		Bipolar Loop	62061
Drainage (PCN) Catheter	10735	Ball Bipolar Loop	62061
Drainage (PCN) with Needle	10735	Ball Electrode	62061
Drainage (PCN) Catheter Set	10735	<b>10.Stone Basket - Class IIa</b>	
Drainage (PCN) Set with Needle	10735	Stone Basket Nitinol (Z)	35808
<b>3.Suprapubic Catheter and Set - Class IIa</b>		Stone Grasper	35808
Suprapubic Catheter Set	34924	URS Forceps	35808
Suprapubic Cysto Catheter Set	34924	PCN Basket (Perk)	35808
<b>4.Ureteral Catheter - Class IIa</b>	34926	<b>11. Ureteral Balloon Dilator - Class IIa</b>	
<b>5.Dilators - Class IIa</b>		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
<b>6.Needles - Class IIa</b>		<b>12.Evacuator - Class IIa</b>	37143
IP Needle	32337	<b>13.Ureteral Stent (Double J Stent) - Class IIb</b>	47035
Chiba Needle	32337		
Biopsy Gun	12734		
<b>7-Dual Lumen,Ureteral Catheter- Class IIa</b>	34926		