



CERTIFICATE

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.



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		





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	: M.2016.106.6518
Ataskaitos numeris	: UD.3098.YB
Pradinio vertinimo data	: 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		

EC CERTIFICATE

Certificate No 057/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

PIRRONE & CO. SPA

20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

manages in the factories of:

PIRRONE & CO SPA - 20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

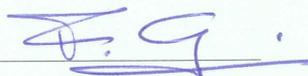
Recording charts for medical equipment

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned).

Reference to IMQ files Nos: 10A9800089; 10EK00036.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 1998-06-29
Updated: 2010-07-01
Substitution Date: 1999-01-19


IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2015-06-30 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

CERTIFICATO CE

Certificato n. 057/MDD

Dichiarazione di approvazione del sistema qualità (Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

PIRRONE & CO. SPA

20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

mantiene negli stabilimenti di:

PIRRONE & CO SPA - 20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte diagrammate per apparecchiature elettromedicali

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione).

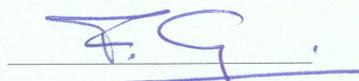
Riferimento pratiche IMQ: 10A9800089; 10EK00036.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 1998-06-29

Data di Aggiornamento: 2010-07-01

Sostituisce: 1999-01-19



IMQ

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".
Essa non è comunque valida dopo il 2015-06-30 (articolo 11, comma 11 della direttiva).

CERTIFICATO CE

Certificato n. 1310/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

PIRRONE & CO. SPA

20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

mantiene negli stabilimenti di:

PIRRONE & CO SPA - 20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Accessori per elettrobisturi

Serie: EUROPLATE Modd. 12719;12720;12721;12722;12726;12728;12729.

Marca PIRRONE & CO S.p.A.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale).

Riferimento pratiche IMQ: 10AK00022; 10EK00036.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2010-02-25
Data di Aggiornamento: 2010-07-01
Sostituisce: 2010-02-25


IMQ

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".
Essa non è comunque valida dopo il 2015-02-24 (articolo 11, comma 11 della direttiva).

EC CERTIFICATE

Certificate No 1310/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II of the Directive 93/42/EEC and its revised version, we hereby certify that:

PIRRONE & CO. SPA

20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

manages in the factories of:

PIRRONE & CO SPA - 20139 MILANO (MI) - VIA BALDUCCIO DA PISA 12 (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

Accessories for electrosurgical units

Series: EUROPLATE Type ref. 12719;12720;12721;12722;12726;12728;12729.

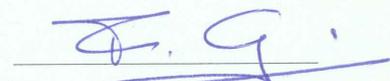
Trade mark PIRRONE & CO S.p.A.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing).

Reference to IMQ files Nos: 10AK00022; 10EK00036.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2010-02-25
Updated: 2010-07-01
Substitution Date: 2010-02-25


IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2015-02-24 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

EC SERTIFIKATAS

Sertifikato Nr. 0 5 7/MDD

Produkcijos Kokybės Garantinis Patvirtinimo Sertifikatas

Remiantis mūsų įvertinimu pagal V priedą, 3 skirsnis, ir atsižvelgiant į VII priedą, 5 direktyvos 93/42EEC ir jos peržiūrėtos versijos skirsnį, patvirtiname, kad:

PIRRONE&CO S.p.A.

20139 MILANO (MI) – VIA BALDUCCIO DA PISA 12 (ITA) - ITALY

valdo gamyklas:

PIRRONE & CO SPA – 20139 MILANO (MI) – VIA BALDUCCIO DA PISA 12
(ITA) ITALY

produkcijos kokybės užtikrinimo sistema patvirtina šių produktų kokybę:

Rašomasis popierius medicininei įrangai

pagal atitinkamus ankščiau minėtos direktyvos reikalavimus (kiek tai liečia visus gamybos etapus).

Nuoroda į IMQ failus: 10A9800089; 10EK00036; 10EN00021;DM15E0379603-01

Šis patvirtinantis sertifikatas yra išduotas IMQ, kuris įgaliotas už direktyvą
93/42/EEC

Įgaliotasis pripažintas Europos komisijos pagal numerį: 0051

Data: 1998-06-29

Atnaujinta: 2015-06-17

Pakeitimo data: 2013-03-19

/parašas/
IMQ

Šis patvirtinimo sertifikatas bus peržiūrimas pagal „Medicinos prietaisų CE Sertifikavimo valdymo taisyklės pagal Direktyvą 93/42/EEB“





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 045257 0042 Rev. 00

Transjugular Sets
Percutaneous Cholangiography Catheters and Sets
Pressure Monitoring Arterial Sets
Peritoneal Lavage Sets
Anchoring Devices
Catheter Repair Sets
Respiratory Management Sets
Thoracentesis Drainage Sets
Laposcopic Endobiliary Stent Systems
Subcutaneous Tunneling Devices
Enteral Feeding Tubes
Urology Wire Guides
Percutaneous Peritoneal Dialysis & Hemofiltration Sets
Urinary Tract Catheters
Short Term Percutaneous/Nephrostomy Devices
Aspiration Infusion Needles
Dilators & Dilator Sets
Suture Devices
Introducer/Access Devices
Manipulation/Removal Devices
Wire Guides
Hemostasis Devices
Amniocentesis Tray/Amniocentesis Needle
Instillation/Aspiration Devices
Drainage Devices
Biopsy Tissue Sampling Devices & Trays
Patency Devices
Surgical Knives
Invasive Urinary Tract Measurement Devices
Invasive Dilators & Dilator Sets
Localize, Hold or Stabilize Devices
Endoscopic Devices

Class III Products

Five Lumen Central Venous Catheter Sets
Spectrum and Spectrum Glide
Central Venous Catheter Sets
Heparin Coated Pressure Monitoring Central Venous and Atria Sets
Diagnostic Heart Catheters
Embolization Devices
Polyvinyl Alcohol Foam Embolization Particles
Occlusion Balloon Catheters
Angiographic Catheters
Diagnostic Cerebral Catheters
Specialty Introducer Sets
Parenteral Nutrition Central Venous Sets
Pericardiocentesis Drainage Sets
Pressure Monitoring Central Venous and Atria Sets
Intravascular Retrieval Sets
Intracardiac Devices

Page 2 of 4

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 045257 0042 Rev. 00

**Transseptal Needles
Embolotherapy and / or Guiding Catheters
Selective Infusion Delivery Devices Microcatheters
Vena Cava Filter Sets
Central Venous Hemodialysis Sets
Vessel Measure Devices
Abdominal Aortic Aneurysm Endovascular Stent Grafts
Spinal Needles
Central Circulatory Wire Guides**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72153312

Valid from: 2019-11-01

Valid until: 2024-05-26

Date, 2019-10-25

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 045257 0042 Rev. 00

Facility(ies): Cook Incorporated
750 Daniels Way, Bloomington IN 47404, USA

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17