



EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Istanbul Tuzla Deri Org. San. Bölğ. Yan San. Gel. Alan.
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Products: The products defined at the enclosure which is the part of this certificate and contains three page.

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3567.06
Date of first issue: 25 July 2011
Revision Number: 05
Date of last issue: 16 November 2017
Expiry Date: 14 July 2019

16 November 2017, İstanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

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Concerned medical devices;

Name of the products	Types	Product reference code	Class
STONE BASKETS	Nitinol Helical	532XXX	IIa
	Nitinol Flat Wire		
	Nitinol Triprong		
	Nitinol Tipless		
	Nitinol Percutaneous Basket		
URODYNAMIC CATHETERS AND SETS	Urodynamic Cystometry Catheter and Set	545XXX	IIa
	Hydrophilic Urodynamic Cystometry Catheter		
	Urodynamic Cystometry Catheter & UPP Catheter		
	Hydrophilic Urodynamic Cystometry Catheter & UPP Catheter		
RENAL DILATORS AND SETS	Amplatz Renal Sheat	542XXX	IIa
	Amplatz Renal Dilator and Sheat Set		
	Fascial Dilator and Sets		
	Percutaneous Tract Dilatation Kit with Nephrostomy Balloon Dilator		
	Screw Dilator		
	Percutaneous Tract Dilatation Kit with With Amplatz Renal Dilator Set		
URETERAL CATHETERS	Dual Lumen Ureteral Catheters	541XXX	IIa
	Ureteral Catheters	537XXX	
	Hydrophilic Ureteral Catheters	537XXXH	
URETERAL ACCESS SHEAT AND DILATOR SETS	Ureteral Access Sheat& Dilator Set	542XXX	IIa
	Nottingham Dilator Catheter	533XXX	
	Ureteral Dilators and Sets	533XXX	
IUI CATHETER	IUI Catheters & IUI Catheter Cannula	544XXX	IIa
INFLATION DEVICE	INFLATION DEVICE	534XXX	IIa
	INFLATION DEVICE SETS		

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Name of the products	Types	Product reference code	Class
URETERAL STENTS AND SETS	Ureteral Stent and Sets	500XXX 500XXXH 510XXX 510XXXH 520XXX 520XXXH	IIb
	Long Term Ureteral Stent and Sets		
	Hydrophilic Ureteral Stent and Sets		
	Multilength Ureteral Stent and Sets		
	Hydrophilic Multilength Ureteral Stent and Sets		
	Silicone Multilength Ureteral Stent and Sets		
	Long Term Multilength Ureteral Stents and Sets		
	Endopylotomy Stent and Sets		
SUPRAPUBIC CATHETER AND SETS	Suprapubic Catheters and Sets	539XXX	IIa
	Silicone Suprapubic Catheter and Sets	5391XX	
NEEDLES	TLA Introducer Needle	543XXX	IIa
	Initial Puncture Needles		
	Chiba Needle		
CUTTING ELECTRODES	Cutting Electrodes Single Stem	531XXX	IIb
	Cutting Electrodes Double Stem		
	Cutting Loop		
	Roller Loop Double Stem		
GUIDE WIRES	Guide Wire - Nitinol	536XXX	IIa
	Hydrophilic Guide Wire - Nitinol		
	Zebra Guide Wire - Nitinol		
	Guide Wire-PTFE		
BALLOON DILATOR CATHETERS	Ureteral Balloon Dilator	533XXX	IIa
	Nephrostomy Balloon Dilator		
	Transureteroscopic Balloon Dilator		
	Occlusion Balloon Catheter		
MALECOT NEPHROSTOMY CATHETER AND SETS	Malecot Nephrostomy Catheter and Sets	538XXX	IIa
	Re-Entry Malecot Catheter		

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CERTIFICATE

Enclosure of the EC Certificate:

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Name of the products	Types	Product reference code	Class
NEPHROSTOMY CATHETER AND SETS	Nephrostomy Pigtail Catheter and Sets	537XXX 540XXX	IIa
	Nephrostomy Pigtail Catheter and Sets with Trocar Needle	537XXX	
	Nephrostomy Pigtail Catheter and Sets with Locking	540XXX	
	Nephrostomy Pigtail Catheter and Sets with Trocar Needle, Locking	540XXX	
	Hydrophilic Multi Purpose Pigtail Drainage Catheter and Sets Locking, With Needle	540XXXH	
MANUAL RESUSCITATOR	Reusable Manual Resuscitator	130XXX	IIa
	Disposable Manuel Resuscitator		
DISPOSIBLE AIRCUSHION MASK	-		
SILICONE MASK	Silicone Mask		
	Silicone Rendell Barker Mask		
TRACHEOSTOMY MASK	-		
NEPHROSTOMY BALLOON DILATATION CATHETER SET	30F 15CM	533020	IIa
NEPHROSTOMY BALLOON DILATATION CATHETER SET	30F 12CM	533013	IIa
NEPHROSTOMY BALLOON DILATATION CATHETER KIT	30F 15CM	533023	IIa
NEPHROSTOMY BALLOON DILATATION CATHETER KIT	30F 12CM	533024	IIa
INTRACAVITARY HYPERTHERMIA CATHETER SET	-	950151	IIa

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

16 November 2017 , Istanbul, Turkey

Head of Notified Body