

# DECLARATION OF CONFORMITY



**PLASTİ-MED Plastik Medikal Ürünleri San. Ve Tic. Ltd. Şti.**

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**PRODUCT** : UROLOGY PRODUCTS- Products are defined in Annex 1.  
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**NOTIFIED BODY NO** : 1984  
**CERTIFICATE NO** : 1984-MDD-11-100  
**CERTIFICATION ROUTE:** ANNEX II FULL QUALITY MANAGEMENT SYSTEM ( EXCEPT FOR SECTION 4)  
**CLASSIFICATION RULE:** CLASS IIA/IIB RULE 5 MDD 93/42/EEC (2007/47/EC) Medical Device Directive according to Annex IX

## Models

REF NO	PRODUCT NAME	GMDN CODE	SINIF	REF NO	PRODUCT NAME	GMDN CODE	CLASS
532XXX	STONE BASKETS	46452	Ila	543XXX	NEEDLES	32337	Ila
545XXX	URIDYNAMIC CATHETERS AND SETS	32089	Ila	531XXX	CUTTING ELECTRODES	11490	Ilb
542XXX	RENAL DILATORS AND SETS	46448	Ila	536XXX	GUIDE WIRES	45623	Ila
541XXX 537XXX 537XXXH	URETERAL CATHETERS	34926	Ila	533XXX	BALLOON DILATOR CATHETERS	11265	Ila
542XXX 533XXX	URETERAL ACCESS SHEAT AND DILATOR SETS	11265 38821	Ila	538XXX	MALECOT NEPHROSTOMY CATHETER AND SETS	10735	Ila
500XXX 500XXXH 510XXX 510XXXH 520XXX 520XXXH	URETERAL STENTS AND SETS	47035	Ilb	537XXX 540XXX 540XXXH	NEPHROSTOMY CATHETER AND SETS	10735	Ila
539XXX 5391XX	SUPRAPUBIC CATHETER AND SETS	34924	Ila	544XXX	IUI CATHETER AND IUI CATHETER CANNULA	32655	Ila

that the following described product in our delivered version complies with the appropriate basic safety and health requirements of the Medical Device Directive 93/42/EEC (2007/47/EC) based on its design and type, as brought into circulation by us. In case of alteration of the device, not agreed upon by us, this declaration will lose its validity.

**Issue Date** : 25.07.2011  
**Name** : MUAMMER BERKSÖZ  
**Position** : GENERAL MANAGER

**Signature** : 

## ANNEX – 1

Product Name	Product Types	Ref No	Class
STONE RETRIEVAL BASKETS	Nitinol Helical	532XXX	IIa
	Nitinol Flat Wire		
	Nitinol Triprong		
	Nitinol Tipless		
	Nitinol Percutaneous Basket		
URIDYNAMIC 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 Sheath	542XXX	IIa
	Amplatz Renal Dilator Sheath 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 SHEATH AND DILATOR SETS	Ureteral Access Sheath & Dilator Set	542XXX	IIa
	Nottingham Dilator Catheter		
	Ureteral Dilators and Sets		
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 Catheters 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		

Product Name	Product Types	Ref No	Class
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		
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	
INFLATION DEVICE	Inflation Devices	534XXX	IIa
	Inflation Devices Sets		
IUI	IUI Catheter&IUI Catheter Cannula	544XXX	IIa