

## 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

Deri OSB Mahallesi. Yan Sanayi Cad. No:13 Tuzla/İstanbul/Turkey

The products defined at the enclosure which is the part of this certificate and contains six pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.3567.09  
**Date of first issue:** 25 July 2011  
**Date of last issue:** 25 May 2021  
**Revision Number:** 11  
**Expiry Date:** 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex II for Class Is devices covered by this certificate and found that the quality system meets the requirements of MDD Annex II.



Muhtesem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey

## Enclosure of the EC Certificate:

Full Quality Assurance System according to

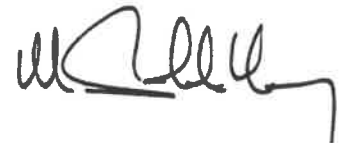
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Stone Baskets	Nitinol Helical
	Nitinol Flat Wire
	Nitinol Triprong
	Nitinol Tipless
	Nitinol Percutaneous Basket
	3 Wires
	Spiral Stone Holder
Urodynamic Catheters And Sets	Urodynamic Cystometry Catheter and Set
	Hydrophilic Urodynamic Cystometry Catheter
	Urodynamic Cystometry Catheter & UPP Catheter
	Hydrophilic Urodynamic Cystometry Catheter & UPP Catheter
Renal Dilator And Sets	Amplatz Renal Sheat
	Amplatz Renal Dilatör and Sheat Set
	Fascial Dilator and Sets
	Percutaneous Tract Dilatation Kit with Nephrostomy Balloon Dilator
	Screw Dilator
	Percutaneous Tract Dilatation Kit with Amplatz Renal Dilator Set
Ureteral Catheters	Dual Lumen Ureteral Catheters
	Ureteral Catheters
	Hydrophilic Ureteral Catheters
Ureteral Access Sheat And Dilator Sets	Hydrophilic Ureteral Access Sheat& Dilator Set
	Ureteral Access Sheat& Dilator Set
	Nottingham Dilator Catheter
	Ureteral Dilators and Sets

Muhtesem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 2/6

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
IUI Catheter	IUI Catheters
	IUI Catheter Cannula
Suprapubic Catheter And Sets	Suprapubic Catheters and Sets
	Silicone Suprapubic catheter and Sets
	Suprapubic Catheter Set-Standard
	Suprapubic Catheter Set With Balloon
Needles	TLA Introducer Needle
	Initial Puncture Needles
	Chiba Needle
Guide Wires	Guide Wire- Nitinol
	Hydrophilic Guide Wire- Nitinol
	Zebra Guide Wire- Nitinol
	Guide Wire-PTFE
	Guide Wire J Type
	Ocean Touch Hydrophilic Tip Zebra Guidewire
Ballon Dilator Catheters	Ureteral Balloon Dilator
	Nephrostomy Balloon Dilator
	Transureteroscopic Balloon Dilator
	Transureteroscopic Ureteral Balloon Dilator and Sets With Hydrophilic Tip
	Ureteral Balloon Dilator and Sets With Hydrophilic Tip
	Occlusion Balloon Catheter
Malecot Nephrostomy Catheter And Sets	Malecot Nephrostomy Catheter and Sets
	Re-Entry Malecot Catheter

Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

Page 3/6

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

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Nephrostomy Catheter And Sets	Nephrostomy Pigtail Catheter and Sets
	Nephrostomy Pigtail Catheter and Sets with Trocar Needle
	Nephrostomy Pigtail Catheter and Sets with Locking
	Nephrostomy Pigtail Catheter and Sets With Trocar Needle, Locking
	Hydrophilic Multi Purpose Pigtail Drainage Catheter and Sets Locking, with Needle
Nephrostomy Balloon Dilatation Catheter Set	-
	-
Nephrostomy Balloon Dilatation Catheter Kit	-
	-
Intracavitary Hyperthermia Catheter Set	-
Closed Wound Drainage Systems And Accessories	Wound Drainage Sets
	Soft Drains with Drainage Bag
	Wound Drainage Sets with Reservoirs and with Flat Drains
	Flat Drains
	Wound Drainage Reservoir
	Round Silicone Drains
Yankauer Suction Sets And Accessories	Yankauer Suction Sets
	Yankauer Suction Handles
	Aspirator Connecting Tube



Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 4/6

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Biopsy Punch	-
Airway (Guedel Type)	
Poche Perforator	-
Umbilical Cord Clamp	-
Bacterial Filters	Bacterial Filter
	Hmef Filter
	Hme Filter
	Hepa Filter
	Bacterial Filter
	HMEF Filter- Elite
HME Filter- Elite	
Smear Brush & Smear Brush Endocervical	Smear Brush Smear Brush Endocervical
Karman Cannula	-
Suction Bag & Canister And Accessories	Suction Bags
	Suction Bag Tubes
	Kapkon Connector
Extension Line	
Three Way Stopcock	-
Breathing And Anesthesia Circuits	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
	Breathing Inhalation- Threatment Chamber
	Breathing and Anesthesia Circuit Accessories

Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, İstanbul, Turkey

Enclosure of the EC Certificate:

Page 5/6

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Arthroscopy Set Y (T.U.R)	Arthroscopy Set Y (T.U.R.)
	Arthroscopy Set with Manual Pressure Pump (T.U.R.)
Blood Gas Syringe With Needle	-
Endometrial Cell Sampler	-
Disposable Oral Swab	-
Sponge Swab	-
Ureteral Stents And Sets	Ureteral Stent and Sets
	Long Term Ureteral Stent and Sets
	Hydrophilic Ureteral Stent and Sets
	Multilenght Ureteral Stent and Sets
	Hydrophilic Multilenght Ureteral Stent and Sets
	Silicone Multilenght Ureteral Stents and Sets
	Endopylotomy Stent and Sets
Cutting Electrodes	Cutting Electrodes Single Stem
Enteral Feeding Bag	Single
	Double
Sterile Karman Syringe	Single Valve, Single Valve Set-Sterile
	Double Valve, Double Valve Set-Sterile

Non- Sterile medical Devices

Product Name	Types
Manual Resuscitator	Reusable Manuel Resuscitator
	Disposable Manuel Resuscitator
	Reusable Manuel Resuscitator Sets
	Disposable Manuel Resuscitator Sets



Muhteşem Gökhan Yücel  
Head of Notified Body

25 May 2021, Istanbul, Turkey

**Enclosure of the EC Certificate:**  
**Full Quality Assurance System according to**  
**Medical Devices Directive 93/42/EEC Annex-II Section 3**  
**Certificate Number: 1984-MDD-11-100, Revision Number: 11**

Concerned medical devices;  
 Non-Sterile medical devices

Product Name	Types
Disposable Air Cushion Mask	Neonatal
	Infant
	Pediatric
	Child
	Small Adult
Silicone Mask	Adult
	Neonatal
	Infant
	Pediatric
	Child
Respiratory Masks and Accessories	Small Adult
	Adult
	Oxygen Masks and Accessories
	Nebulizer Set and Accessories
Karman Syringe	High Concentration Oxygen Mask
	Nasal Oxygen Cannula
Suction Bag & Canister And Accessories	Single Valve, Single Valve Set
	Double Valve, Double Valve Set
Breathing And Anesthesia Circuits	Suction Bags
	Suction Canister
	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
CPAP BPAP Masks	Breathing Inhalation- Threatment Chamber
	Breathing and Anesthesia Circuit Accessories
	Ora-Nasal
	Nasal

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel  
 Head of Notified Body

25 May 2021, Istanbul, Turkey