

## 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 eight pages.

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

**Report Number:** M.3567.08

**Date of first issue:** 25 July 2011

**Date of last issue:** 16 July 2020

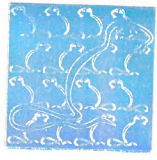
**Revision Number:** 10

**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.

Muhteşem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey



# CERTIFICATE

Enclosure of the EC Certificate:

Page 1/8

Full Quality Assurance System according to

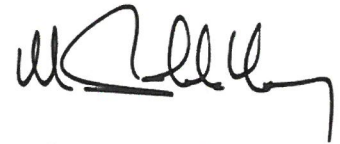
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

Sterile medical devices

Product Name	Types
Stone Baskets	Nitinol Helical
	Nitinol Flat Wire
	Nitinol Triprong
	Nitinol Tipless
	Nitinol Percutaneous Basket
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	Ureteral Access Sheat& Dilator Set
	Nottingham Dilator Catheter
	Ureteral Dilators and Sets



Muhteşem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey

# CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to

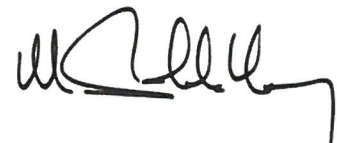
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 10

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
Needles	TIA Introducer Needle
	Initial Puncture Needles
	Chiba Needle
Guide Wires	Guide Wire- Nitinol
	Hydrophilic Guide Wire- Nitinol
	Zebra Guide Wire- Nitinol
	Guide Wire-PTFE
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
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



Muhtesem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey



# CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to

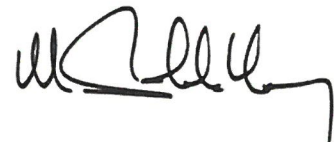
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

Sterile medical devices

Product Name	Types
Nephrostomy Balloon Dilatation Catheter Set	30F 15cm 30F 12cm
Nephrostomy Balloon Dilatation Catheter Kit	30F 15cm 30F 12cm
Intracavitary Hyperthermia Catheter Set	950151
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
Spirometer Filters	Round Silicone Drains
	Elliptic Mouth
	Circular Mouth
	Graded Mouth - Cartoon Mouth
Yankauer Suction Sets And Accessories	Circular Mouth - Cartoon Mouth
	Yankauer Suction Sets
	Yankauer Suction Handles
Biopsy Punch	Aspirator Connecting Tube
	230101
	230102
	230103
	230104



Muhteşem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey



# CERTIFICATE



Enclosure of the EC Certificate:

Page 4/8

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

Sterile medical devices

Product Name	Types
Airway	200101
	200102
	200103
	200104
	200105
	200106
	200107
	200108
	200109
Poche Perforator	150201
Umbilical Cord Clamp	150101
Bacterial Filters	Bacterial Filter
	Hmef Filter
	Hme Filter
	Hepa Filter
	Bacterial Filter
	HMEF Filter- Elite
Smear Brush	HME Filter- Elite
	Smear Brush
	Smear Brush Endocervical

Muhteşem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey



# CERTIFICATE

Enclosure of the EC Certificate:

Page 5/8

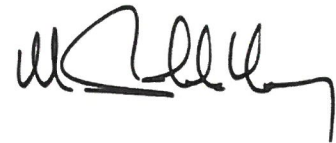
Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;  
Sterile medical devices

Product Name	Types
Karman Cannula	240111
	240112
	240113
	240114
	240115
	240116
	240117
	240118
	240119
Suction Bag & Canister And Accessories	Suction Bags
	Suction Bag Tubes
	Kapkon Connector
Extension Line	310030
	310045
	310060
	310075
	310090
	310120
	310145
	310200
	320030
	320045
	320060



Muhteşem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey





Enclosure of the EC Certificate:

Page 6/8

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

Sterile medical devices

Product Name	Types
Extension Line	320075
	320090
	320120
	320145
	320200
	320210
	325030
	325045
	325060
	325075
	325090
	325120
	325145
	325200
Three Way Stopcock	301001
Breathing And Anesthesia Circuits	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
	Breathing Inhalation- Treatment Chamber
	Breathing and Anesthesia Circuit Accessories
Arthroscopy Set Y (T.U.R.)	Arthroscopy Set Y (T.U.R.)
	Arthroscopy Set with Manual Pressure Pump (T.U.R.)

Muhteşem Gökhan Yücel  
Head of Notified Body

16 July 2020, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 7/8

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

Sterile medical devices

Product Name	Types
Blood Gas Syringe	210301
	210302
	210321
	210322
Endometrial Cell Sampler	240201
Disposable Oral Swab	490101
Sponge Swab	490104
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 Multilength Ureteral Stents and Sets
	Endopylotomy Stent and Sets
Cutting Electrodes	Cutting Electrodes Single Stem

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

16 July 2020, Istanbul, Turkey



## Enclosure of the EC Certificate:

Full Quality Assurance System according to

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

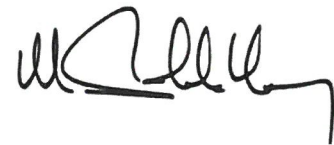
Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

Non - Sterile medical devices

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

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

16 July 2020, Istanbul, Turkey