

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: 11 February 2020
Revision Number: 09
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

11 February 2020, Istanbul, Turkey

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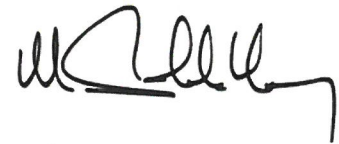
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 09

Concerned medical devices;

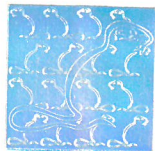
Sterile medical devices

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



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Product Name	Types	Class
IUI Catheter	IUI Catheters	Ila
	IUI Catheter Cannula	Ila
Suprapubic Catheter And Sets	Suprapubic Catheters and Sets	Ila
	Silicone Suprapubic catheter and Sets	Ila
Needles	TIA Introducer Needle	Ila
	Initial Puncture Needles	Ila
	Chiba Needle	Ila
Guide Wires	Guide Wire- Nitinol	Ila
	Hydrophilic Guide Wire- Nitinol	Ila
	Zebra Guide Wire- Nitinol	Ila
	Guide Wire-PTFE	Ila
Ballon Dilator Catheters	Ureteral Balloon Dilator	Ila
	Nephrostomy Balloon Dilator	Ila
	Transureteroscopic Balloon Dilator	Ila
	Transureteroscopic Ureteral Balloon Dilator and Sets With Hydrophilic Tip	Ila
	Ureteral Balloon Dilator and Sets With Hydrophilic Tip	Ila
	Occlusion Balloon Catheter	Ila
Malecot Nephrostomy Catheter And Sets	Malecot Nephrostomy Catheter and Sets	Ila
	Re-Entry Malecot Catheter	Ila
Nephrostomy Catheter And Sets	Nephrostomy Pigtail Catheter and Sets	Ila
	Nephrostomy Pigtail Catheter and Sets with Trocar Needle	Ila
	Nephrostomy Pigtail Catheter and Sets with Locking	Ila
	Nephrostomy Pigtail Catheter and Sets With Trocar Needle, Locking	Ila
	Hydrophilic Multi Purpose Pigtail Drainage Catheter and Sets Locking, with Needle	Ila

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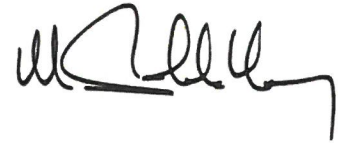
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Sterile medical devices

Product Name	Types	Class
Nephrostomy Balloon	30F 15cm	Ila
Dilatation Catheter Set	30F 12cm	Ila
Nephrostomy Balloon	30F 15cm	Ila
Dilatation Catheter Kit	30F 12cm	Ila
Intracavitary Hyperthermia Catheter Set	950151	Ila
Closed Wound Drainage Systems And Accessories	Wound Drainage Sets	Ila
	Soft Drains with Drainage Bag	Ila
	Wound Drainage Sets with Reservoirs and with Flat Drains	Ila
	Flat Drains	Ila
	Wound Drainage Reservoir	Ila
Spirometer Filters	Elipitic Mouth	Ila
	Circular Mouth	Ila
	Graded Mouth - Cartoon Mouth	Ila
	Circular Mouth - Cartoon Mouth	Ila
Yankauer Suction Sets And Accessories	Yankauer Suction Sets	Ila
	Yankauer Suction Handles	Ila
	Aspirator Connecting Tube	Is
Biopsy Punch	230101	Ila
	230102	Ila
	230103	Ila
	230104	Ila



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

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

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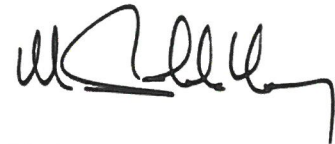
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Product Name	Types	Class
Extension Line	320075	Ila
	320090	Ila
	320120	Ila
	320145	Ila
	320200	Ila
	320210	Ila
	325030	Ila
	325045	Ila
	325060	Ila
	325075	Ila
	325090	Ila
	325120	Ila
	325145	Ila
	325200	Ila
Three Way Stopcock	301001	Ila
Breathing And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



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Product Name	Types	Class
Blood Gas Syringe	210301	Ila
	210302	Ila
	210321	Ila
	210322	Ila
Endometrial Cell Sampler	240201	Is
Disposable Oral Swab	490101	Is
Sponge Swab	490104	Ila
Ureteral Stents And Sets	Ureteral Stent and Sets	Ilb
	Long Term Ureteral Stent and Sets	Ilb
	Hydrophilic Ureteral Stent and Sets	Ilb
	Multilenght Ureteral Stent and Sets	Ilb
	Hydrophilic Multilenght Ureteral Stent and Sets	Ilb
	Silicone Multilengthh Ureteral Stents and Sets	Ilb
Cutting Electrodes	Endopylotomy Stent and Sets	Ilb
	Cutting Electrodes Single Stem	Ilb

Non- Sterile medical Devices

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

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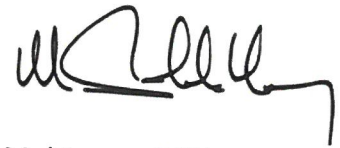
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Non - Sterile medical devices

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

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



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11 February 2020, Istanbul, Turkey

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