

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:

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

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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 |



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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 |

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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 |



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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 |

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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 |



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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



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 Head of Notified Body

25 May 2021, Istanbul, Turkey