

EC Certificate

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

Certificate Number: 1984-MDD-18-521

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:

**OPTİMAL SAĞLIK ÜRÜNLERİ
SANAYİ VE DIŞ TİCARET LİMİTED ŞİRKETİ**

Firuzköy Mah. Poyraz Caddesi Mesken Apt. no:100/A
Avcılar, Istanbul, Turkey

Products: Sterile surgical sets, surgical gowns, surgical drapes

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

Report Number: M.3767.07

Expiry Date: 17 May 2021



18 May 2018, Istanbul, Turkey

Head of Notified Body



CERTIFICATE



Enclosure of the EC Certificate:

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Concerned medical devices;

Name of the product: Eye packs **Class:** Is
Types: Standard Eye Pack, Eye Pack Basic, Eye Pack Plus, Standard Phaco Pack, Minor Phaco Pack, Sitrabismus Pack, Oculoplasty Pack, D.C.R. Pack, Chalazion Pack, Ptergium Pack, Cornea Transplantation Pack, Edge Pack, Lid Pack, Detachment Pack, Vitrectomi Pack

Name of the product: Neurosurgery Packs **Class:** Is
Types: Neurosurgery Pack, Shunt Pack, Craniotomi Pack, Spinal Pack

Name of the product: Angiography and Cardiovascular Packs **Class:** Is
Types: Angiography Pack, Angioplasty Pack, By-Pass Pack, Valve Replacement Pack, Cardiovascular Thoracic Pack

Name of the product: General Surgery Packs **Class:** Is
Types: General Surgery Pack, Laparoscopy Pack, Laparotomy Pack, Minor Surgery Pack, Dressing Pack, Plastic Surgery Pack, Abdominal Pack, Suture Pack

Name of the product: Oncology Packs **Class:** Is
Types: Chemotherapy Pack, Biopsy Pack

Name of the product: Urology Packs **Class:** Is
Types: Cystoscopy Pack, TUR Pack, Urology Pack, Percutaneous Pack

Name of the product: ENT Packs **Class:** Is
Types: ENT Pack, Throid Pack

Name of the product: Orthopedic Packs **Class:** Is
Types: Extremity Pack, Lower Extremity Pack, Upper Extremity Pack, Hand Surgery Pack, Hip Pack, Shoulder Pack, Artroskopy Pack

Name of the product: Dental Packs **Class:** Is
Types: Dental Pack, Implant Pack

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Enclosure of the EC Certificate:

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Concerned medical devices;

Name of the product: Gynecology and Delivery Packs

Class: Is

Types: Delivery Pack, Gynecology Pack, Cesarean Pack, Abortion Pack, Epidural Anesthesia Pack, Lithotomy Pack, Fertility Pack, IVF Pack, OPU Pack, E.T. Pack, Perineal Pack

Name of the product: Other Packs

Class: Is

Types: Welcome Pack, Circumcision Pack, Hair Implantation Pack, Veterinary Pack, Drape Pack, Intensive Care Pack, Liposuction Pack, Nefrology Pack

Name of the product: Disposable Surgical Gowns

Class: Is

Types: Sterile Full Reinforced Surgical Gowns, Sterile Reinforced Surgical Gowns, Sterile Standard Surgical Gowns, Urology Gowns, Nurse Gowns

Name of the product: Disposable Surgical Drapes

Class: Is

Types: Drapes (Liquid Repellent), Drapes (Liquid Absorbent), Adhesive Liquid Repellent Drapes, Adhesive Liquid Absorbent Drapes, Liquid Repellent, Fenestrated Drapes, Liquid Absorbent Fenestrated Drapes, Adhesive Liquid Repellent Drapes (Fenestrated), Adhesive Liquid Absorbent Drapes (Fenestrated), Liquid Repellent Split Drapes, Liquid Absorbent Split Drapes, Foot Drapes, Transparent Drapes, Operation Underlay Drapes, Eye Drape with Single LCP, Eye Drape with Double LCP, Eye Drape without LCP, Excimer Laser Drape with Single LCP, Excimer Laser Drape with Double LCP, Excimer Laser Drape, without LCP, By-Pass Drapes, By-Pass Split Drapes, Angiography Drapes, Femoral Angiography Drapes, Angiography Drapes with Transparent Panel, Valve Drapes, TUR Drapes, Li Percutaneous Drapes, Cystoscopy Drapes



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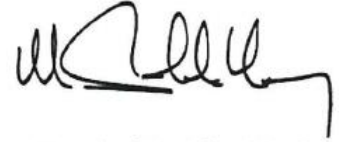
Concerned medical devices;

Name of the product: Disposable Surgical Drapes

Class: Is

Types: Anesthesia Drapes, Laparoscopy Drapes, Minor Surgery Drapes(Fenestrated), Fenestrated Patient Drapes, Patient Top Drapes, Reflector Drapes, ENT U Drapes, ENT Split Drapes, Head Drapes, Caserean Drapes, Gynecology Split Drapes, Abdominal Drapes, Baby Drapes, Suture Drapes, Arthroscopy Drapes, Shoulder Drapes, Hip Drapes, Extremity Drapes (Elastic Fenestrated), Extremity Drapes, Hand Surgery Drapes (Fenestrated), Hand Bottom Drape, Hand Top Drape, Turnique Drape, Fenestrated Arm Drapes, Orthopedic U Drapes, Neurosurgery Drapes, Fertility Drapes, Biopsy Drapes, Back Table Covers, Mayo Table Covers, Fluoroscopy Covers, Camera Covers, Microscope Covers and Drapes, Legging and Foot Covers, Litte Drapes, Bed Covers

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

A handwritten signature in black ink, consisting of a series of loops and strokes, positioned above the title "Head of Notified Body".

18 May 2018, Istanbul, Turkey

Head of Notified Body