



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

Certificate Number: 1984-MDD-16-402

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:

GEOTEK MEDİKAL VE SAĞLIK HİZMETLERİ
TİCARET SANAYİ LİMİTED ŞİRKETİ

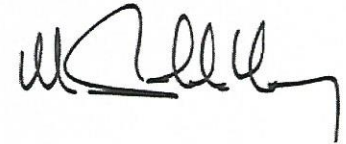
İvedik OSB Ağaç Metal İşleri Sitesi 1436 Sokak No:12, Yenimahalle Ankara, Turkey

Products: Sterile biopsy needles and sets, needle guides and kits, Double J ureteral stents, nephrostomy and drainage catheters, nephrostomy and drainage sets, ureteral catheters, dilators, stone baskets

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

Report Number: M.4660.06
Date of first issue: 29 September 2016
Date of last issue: 28 February 2019
Revision Number: 01
Expiry Date: 27 February 2024

28 February 2019, Istanbul, Turkey



Head of Notified Body

**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-16-402, Revision Number: 01**

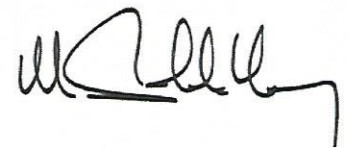
Concerned medical devices;

Product: Sterile biopsy needles and sets

Types
Percutan Access Needle
Semi-automatic Biopsy Needle
Automatic Biopsy Needle
Automatic Biopsy Gun
Automatic Biopsy Gun Needles
Breast Localization Needle
Bone Biopsy Needle
Oocyte Aspiration Needle
Coaxial Needle & set
Amniosynthesis Needle
Seldinger Needle
Bone Marrow Biopsy Needle
Bone Marrow Aspiration Needle
Chiba Biopsy Needle
Franseen Biopsy Needle
Westcott Biopsy Needle
TRUS Biopsy Kit (Transrectal Ultrasonography Biopsy Kit)
Tumor Marker System

Product: Sterile needle guides and kits**Product: Sterile double J ureteral stent**

Types
One End Close / Both Ends Open
Stent Kit With Guide Wire And Clamp
DJ+Pusher
Long durable
Adjustable / Variable (Multiloop)
Single J



Head of Notified Body

28 February 2019, Istanbul, Turkey

Kiwa Certification Services Inc.

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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-16-402, Revision Number: 01**

Concerned medical devices;

Product: Sterile nephrostomy and drainage catheters

Types
Pigtail With Or Without Locking
Direct Puncture With Or Without Locking
Malecot
Suprapubic

Product: Sterile Ureteral Catheter

Types
Open End
Close End

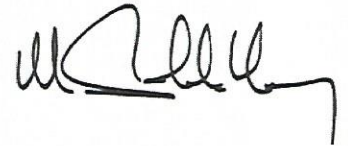
Product: Sterile Dilators

Types
Ureteral Dilator
Balloon Dilator
Access Sheath

Product: Sterile stone baskets

Types
Stainless Steel
Nitinol
Tippless / Zero Tip
Grasper

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



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