CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-14-289

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:

TEKNO MAR MAKİNA İMALAT İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Ostim Osb Mahallesi 1269. Cadde No:29/ - Yenimahalle/ Ankara, Turkey

Products: Hydrogen Peroxide Plasma Sterilization Equipment, Hydrogen Peroxide Ozone Plasma Sterilization Equipment, Ethylene Oxide Sterilization Equipment, Topical Vacuum Treatment Unit, Topical Vacuum Treatment Set, Hydrogen Peroxide Solution Cartridge, Canister / Collecting Unit

The products defined at the enclosure which is the part of this certificate and contains one (1) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.4296.08
Date of first issue: 03 July 2014
Date of last issue: 07 April 2021
Revision Number: 06
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions in accordance with MDD Annex II and found that the quality system meets the requirements of MDD Annex II.

Muhteşem Gökhan Yücel
Head of Notified Body

07 April 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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CERTIFICATE

Enclosure of the CE Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-14-289, Revision Number: 06

Concerned medical devices;

Product Name: Hydrogen Peroxide Plasma Sterilization Equipment
Type: HRF 3000
Models: S30, S75, D75, S125, D125, S175, D175, STEK, DTEK
Type: B Science
Models: BS30, BS75, BD75, BS125, BD125, BS175, BD175, BSTEK, BDTEK,
Product Name: Hydrogen Peroxide Ozone Plasma Sterilization Equipment
Type: HRF 3000 Ozone
Models: 3S30, 3S75,3D75, 3S125, 3D125, 3S175, 3D175, 3STEK, 3DTEK,
Type: B Science
Models: B3S30, B3S75, B3D75, B3S125, B3D125, B3S175, B3D175, B3STEK, B3DTEK
Product Name: Ethylene Oxide Sterilization Equipment
Type: ETO C 1445
Models: Hospital type 80, 125, 134, 157, 175, 210, 300, 500, 700, 800, 1000, 1500, 1700, 2000lt
Industrial type 5; 10,5; 15,5; 20,5; 27; 34; 51; 62,5; ext m^3
Product Name: Topical Vacuum Treatment Unit
Type: Topivac, Careoxi
Models: Hand T-NPWT, Hand T-NPWT Irrigation, Medium (V1, V2, V3, Clinic/V4), TOPI T-NPWT (A100 – A200)
Product Name: Topical Vacuum Treatment Set
Type: Topivac, Careoxi
Models: Topiset, Multidress, Multicase, Canister, Ozon Bag
Product Name: Hydrogen Peroxide Solution Cartridge
Models: A150 HRF 3000, A250 HRF 3000, B150 BSCIENCE, B250 BSCIENCE
Product name: Canister / Collecting Unit
Type: Topivac, Careoxi
Topivac Models: TPVCA1000, TOPIVAC TPVCA1000, TOPISET TPVCA1000, MULTIDRESS TPVCA1000, TPVCA 500, TOPIVAC TPVCA500, TOPISET TPVCA500, MULTIDRESS TPVCA500, CANISTER 1000ml
Careoxi Models: CTPVCA1000, CAREOXI CTPVCA1000, TOPISET CTPVCA1000, MULTIDRESS CTPVCA1000, CTPVCA500, CAREOXI CTPVCA500, TOPISET CTPVCA500, MULTIDRESS CTPVCA500, CANISTER 1000ml

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

07 April 2021, Istanbul, Turkey

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