

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

Certificate Number: 1984-MDD-10-030

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:

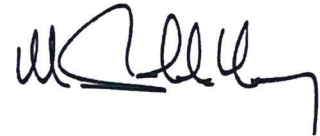
NÜVE SANAYİ MALZEMELERİ
İMALAT ve TİCARET ANONİM ŞİRKETİ

Saracalar Mahallesi Saracalar Kümeevleri No:4/2 Akyurt Ankara, Turkey

Products: Steam Sterilizers, Dry Heat Sterilizers, Blood Bank Refrigerators, Deep Freezers, Platelet Incubators, High Capacity Refrigerated Centrifuge, 3 Gas (Carbon Dioxide, Oxygen and Nitrogen) Incubators

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

Report Number: M.3158.12
Date of first issue: 31 May 2010
Date of last issue: 20 May 2021
Revision Number: 10
Expiry Date: 18 February 2024



Muhteşem Gökhan Yücel
Head of Notified Body

20 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

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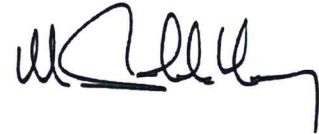
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-030, Revision Number:10

Concerned Medical Devices;

Product	Model
Steam Sterilizers	NC 23B, NC 23S, NC 32S, NC 100, NC 150, NC 150D, NC 300, NC 430, NC 430D, NC 570, NC 570D, NC 710, NC 710D, NC 40M, NC 90M, NC 300L, NC 430L, NC 430LD, NC 570L, NC 570LD, NC 710L, NC 710LD
Dry Heat Sterilizers	FN 300, FN400, FN 500, FN 032, FN 032N, FN 055, FN 055N, FN 120, FN 120N
Blood Bank Refrigerators	KN 72, KN 120, KN 294, KN 504
Deep Freezers	DF 290, DF 490, DF 590, ED 290, ED 490, ED 590, EF 290, EF 490, EF 590, FR 290, FR 490, FR 590
Platelet Incubators	PN 150, PN 300
High Capacity Refrigerated Centrifuge	NF 3000R
3 Gas (Carbon Dioxide, Oxygen and Nitrogen) Incubators	EC 163

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



Muhtesem Gökhan Yücel
Head of Notified Body

20 May 2021, Istanbul, Turkey