

NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

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

**Design, Manufacture, Sales And After Sales Services Of Laboratory
And Sterilization Equipments**

with a scope of

ISO 9001:2015

Has established a quality management system in accordance
with international standard.

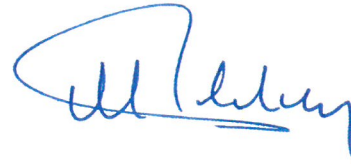
*"Following elements of the standard are excluded "
"None"*

Certificate No : M 8215
Initial Certification Date : 28 April 2010
Certification Date : 11 March 2022
Expiration Date : 10 March 2025

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

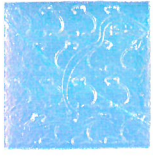
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Certificate is valid till expiration date,
subject to successful completion of
periodical surveillance audits.
Please contact above numbers for
detailed information.



General Manager





CERTIFICATE

NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

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

**Design, Manufacture, Sales And After Sales Services Of Laboratory
And Sterilization Equipments**

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"

"7.5.5" "7.5.7" "7.5.9.2"

Certificate No : M 8216
Initial Certification Date : 28 April 2010
Certification Date : 11 March 2022
Expiration Date : 10 March 2025

Kiwa Belgelendirme Hizmetleri A.Ş.
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General Manager



TÜRKAK BDS NO
YS-FE6F-F002

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

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.3158.10
Date of first issue: 31 May 2010
Date of last issue: 19 February 2019
Revision Number: 08
Expiry Date: 18 February 2024



19 February 2019, Istanbul, Turkey

Head of Notified Body



HPI Verification Services

EU-type Examination Certificate

This is to certify that the product listed below conforms to the requirements of the

Pressure Equipment Directive 2014/68/EU

Annex III Module B(prod)

Certificate Number HPIVS/P1057-048-I-01 rev.1
Date of Issue 15-Nov-2017
Date of Expiry 01-Oct-2027

Designer **NÜVE SANAYİ MALZEMLERİ İMALAT VE TİCARET A.Ş.**
Saracalar Mah. Saracalar Kümeevleri No:4/2
Akyurt /Ankara /Turkey

Description of Pressure Equipment
Steam sterilizer Range : NC 23B, NC23S, NC32S, NC 100, NC 150, NC 150D, NC 40M, NC 90M, NC 300, NC 430, NC 430D, NC 570, NC 570D, NC 710, NC 710D;
Steam generator Range: NC 100, NC 150, NC 300, NC 430, NC 570, NC 710.

Drawing No
N 8467, N 8466, N 8468, N 8475, N 8458, N 8460, N 8463, N 8462, N 8464, N 8461, N 8465, N 7118, N 8040, N 8036, N 6871, N 7987, N 8457, N 7539, N 8359, N 8456 Rev.0 dated 28 Sep 2017; N 8515 Rev.0 dated 19 Oct 2017; N 8497 Rev.0 dated 05 Oct 2017; N 8491 Rev.0 dated 26 Sep 2017

Serial No n/a

Design Pressure PS = 3 bar (for NC 23S, NC 23B, NC 32S PS = 2,6 bar)

Design Temperature Max 144 °C (for NC 23S, NC 23B, NC 32S Max 140 °C)

Standards Used EN 13445

Report Reference HPIVS/P1057-048-DR01 to DR04

This Certificate is valid in any European Economic Area Member State.

This Certificate has been issued by HPI Verification Services Ltd which is a body notified to the European Commission according to the provisions of the Pressure Equipment Directive (Notified Body number 1521).

This Certificate is issued following the assessment of a representative sample of the Pressure Equipment detailed above in accordance with the provisions of the above regulations. The equipment must be subject to an appropriate conformity assessment module during manufacture prior to the CE Mark being affixed.

Check this certificate is genuine



Managing Director

Technical Manager



EU Notified Body No. 1521
Company registered in England #7217086

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