



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 Expiry	01-Oct-2027
Date of Issue	15-Nov-2017		
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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CERTIFICATE

NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

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

**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	: 30 January 2025
Expiration Date	: 29 January 2028

Kiwa Belgelendirme Hizmetleri A.Ş.
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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



TÜRKAK BDS NO
YS-843F-FB1A

Last Modified : 30 January 2025 - R 06



NC 100

Vertical Type Steam Sterilizer



N-s2art

NC 100

VERTICAL TYPE STEAM STERILIZER

NC 100 model Vertical type steam sterilizer has been developed for steam sterilization of textile, glass, packaged or unpackaged materials used in operating rooms, medical, dental, and veterinary faculties of universities, pharmacy, biotechnology, and food sectors.

RELIABLE STERILIZATION

- Built-in steam generator for fast steam generation
- Maintenance-free powerful diaphragm type vacuum pump
- Fractionated pre-vacuum to eliminate all air bubbles and achieve successful steam penetration.
- Fractionated post-vacuum for efficient drying of the samples
- Sterilization quality matching the needs of EN 285 European Standard for Large Steam Sterilizers
- Pre-heated chamber to eliminate condensation on the chamber walls and speed up the heating of the samples



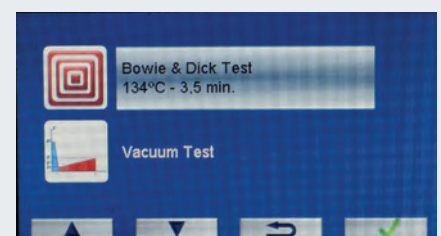
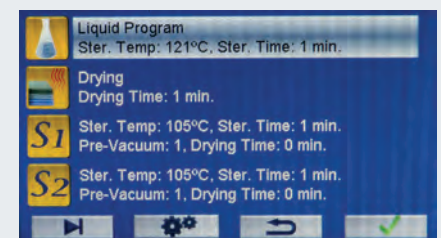
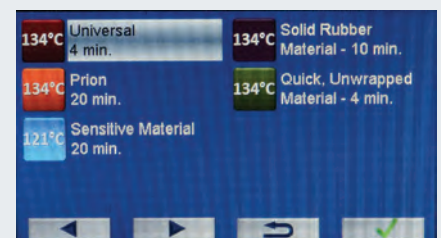
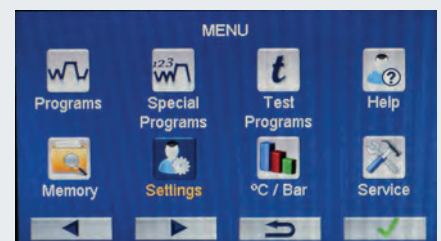


POWERFUL AND RELIABLE CONTROL SYSTEM: N-Smart™

- High resolution 4.3" video graphic color TFT LCD screen with sterilization chamber temperature and pressure, jacket temperature, steam generator temperature and pressure, name of the active program, stage of the program, total and phase times of the active program, sterilization chamber temperature graph, door positions, alarm states traceability
- 4-digit passcode to prevent unauthorized access to the menu
- 5 languages: Turkish, English, French, Spanish, Russian
- Help page with descriptions of device malfunctions

EASY STERILIZATION

- 5 ready-made programs that provide safe sterilization for the materials to be sterilized
 - Universal 134°C 4 minutes
 - Solid rubber material 134°C for 10 minutes
 - Prion 134°C 20 min
 - Quick unwrapped 134°C 4 minutes
 - Sensitive 121°C for 20 minutes
- 10 free programs
 - Temperature: 105°C - 136°C
 - Sterilization time: 1 - 99 minutes
 - Number of pre-vacuums: 1 - 4
 - Drying time: 0-30 minutes
- Two special programs for liquid sterilization and drying
- Preheating feature
- Stand-by system that can be adjusted after the sterilization process is completed

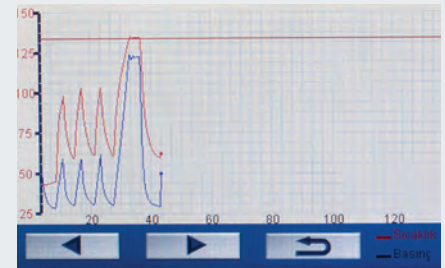


TEST PROGRAMS

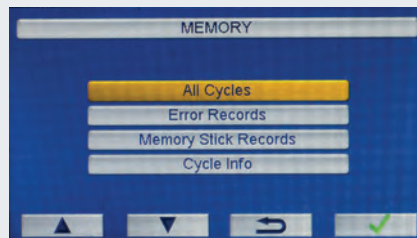
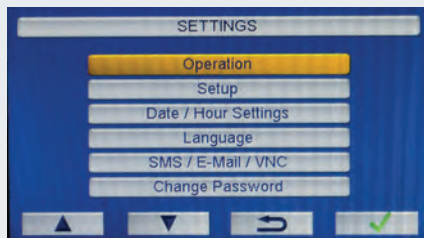
- Vacuum leakage test
- Bowie & Dick test

FULL TRACEABILITY AND REMOTE ACCESS

- Operating parameters can be tracked graphically against time
- Massive data storage with internal memory which stores the records of last 500 cycles in detail and 29.500 cycles as summary
- Memory for the last 100 failures
- USB port to record the operated cycles in the memory to a memory stick.
- Software update via USB port
- Remote access to operating parameters, data in memory, error history, temperature values and other technical data with Ethernet port and optional NüveCloser™ software
- Informing 5 different people by sending an e-mail in case of all failures with the Ethernet port
- Date-time with optional panel type thermal printer, name of the active program, pre-vacuum time, stage information, preheating temperature, sterilization
- Documentation of the sterilization cycle including temperature and pressure of the chamber, sterilization time, drying time, error messages that may occur in the system, date time at the end of the sterilization process, total time and user signature information is provided
- Standard Wi-Fi connection for the N-Mobile™ phone app

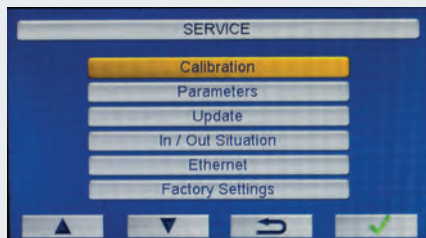


OLDER CYCLES					
NO	DATE	TIME	PROGRAM	STATUS	ERROR
00001	22.09.15	12:16	Bowie & Dick/Helix	✓	---
00002	22.09.15	09:51	Sensitive	✓	---
00003	22.09.15	09:11	Vacuum Test	✓	---
00004	21.09.15	16:26	Prion	✓	---
00005	21.09.15	13:56	Sensitive	✓	---



PROCESS EVALUATION AND ERROR WARNING SYSTEM

- Process evaluation system
- Advanced fault detection system in case of power failure, heater failure, low water level, high temperature and pressure, sensor failures etc



SAFETY ABOVE STANDARDS

- 4-digit password-protected operation, service, and calibration menus
- Electromechanical cover safety system
 - The lid cannot be opened when the chamber is under pressure.
 - The program cannot be started when the lid is open.
- Screen that turns red in case of any alarm and warns the user with the audible alarm
- Reminder for gasket and filter replacement
- Ability to send e-mails to 5 different addresses with detailed information in case of errors and malfunctions
- Optional AlerText™ GSM alarm module, text messages can be sent to 5 different phone numbers in case of errors and malfunctions
- Safety valve against overpressure
- Hepa filter at air intake line
- Accredited institution approved CE marking according to MDD 93/42/EC medical device directive
- Production in accordance with PED 2014/68 EU pressure vessels directive
- Standard validation port



TECHNICAL SPECIFICATIONS

Chamber Volume, liters	104
Sterilization Temperature (in special programs)	105°C to 136°C
Number of Ready Programs	5
Special Program Number	12 (10 solid, 1 liquid*, 1 drying)
Test Programs	Bowie & Dick and vacuum leak testing
Minimum Vacuum Level	200 mbar
Control System	N-Smart™ control system with programmable microprocessor
Display	4.3" color LCD screen
Internal Material	Stainless steel
Standard Accessories	3 pcs sterilization basket (Ø360x242 mm)
Power Rating	7500 W
Power Supply	400VAC, 50 Hz, 3/N/PE
Chamber Dimensions (Diameter x Height)	Ø396x840mm
External Dimensions (WxDxH) mm	890x673x1115
Packing Dimensions (WxDxH) mm	Ø 970x730x1260
Net / Packed Weight, kg	180 / 190

*Please contact us before using the liquid sterilization program

FACTORY FITTED OPTIONS

NC XXX A	Automatic water supply unit
NC XXX Y	Panel type thermal printer
NC 100E	NüveLift™ to load/unload basket

OPTIONS

A 08 191	AlerText™ GSM alarm module (Sim card not included)
A 08 237	NüveCloser™ Software

ACCESSORIES

A 08 104	Printer paper (20 pieces)
F 06 048	HEPA Filter
K 10 065	Basket carrying handle
S 09 038	Perforated sterilization basket with fixed handle (Ø360x242 mm)
S 09 039	Perforated sterilization basket with portable handle (Ø360x242 mm)



NUVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

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ISO 9001: 2015
ISO 13485: 2016
ISO 45001: 2018

