

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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NC 40M / 90M

Laboratory Steam Sterilizers



N-smart

NC 40M/90M

LABORATORY STEAM STERILIZERS

NC 40M / NC 90M laboratory steam sterilizers are specially designed for the steam sterilization of liquid and culture media and also convenient for the sterilization of any labware such as glass and plastics and unpacked solid materials in the laboratories of hospitals, universities and pharmaceutical, food, beverage, dairy and biotechnology industries.

STANDARD FEATURES FOR LIQUID STERILIZATION

- Flexible temperature sensor to measure the temperature of the liquid load directly as the time required to reach the sterilization temperature of liquid is longer compared to solid loads.
- Cooling function with ambient air ventilation over the chamber that decreases the cooling time of liquid loads to the one third of time spent by conventional systems.
- Condensation of steam at the end of the cycle by means of air ventilated cooling system to prevent a sudden drop in the chamber pressure which causes re-boiling.

WELL PRESERVED SENSITIVE MATERIALS

- Second temperature sensor active for solid load sterilization.
- Controlled steam discharge by fractionated exhaust.
- Programmable exhaust rate against sudden temperature and pressure drop to preserve sensitive materials such as glass.





RELIABLE AND POWERFUL CONTROL SYSTEM: N-Smart™

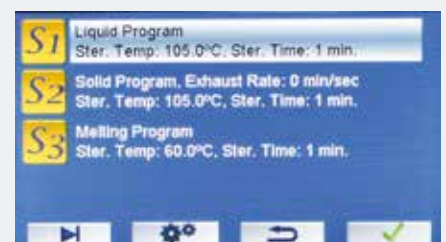
- Maximum information with highly visible 4,3" colourful LCD display
- Four context-sensitive function keys for versatile & easy use
- Password protected menu to secure run parameters and data
- With 5 Language options: Turkish, English, French, Russian, Spanish
- Icons to make the operations easier for immediate understanding

EASY STERILIZATION

- Five pre-set programs which guarantee safe sterilization of the treated material.

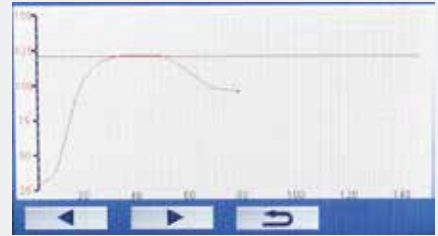
Liquid	121°C	15 minutes
Liquid	121°C	20 minutes
Solid	121°C	20 minutes
Solid	134°C	20 minutes
Solid Quick	134°C	4 minutes

- Two free programs for liquid and solid and a special program for melting purposes which the user can program easily.
- Delayed start function with real time which allows the users to get their samples sterilized on time as they arrive to the laboratory.
- Programmable pre-heating.



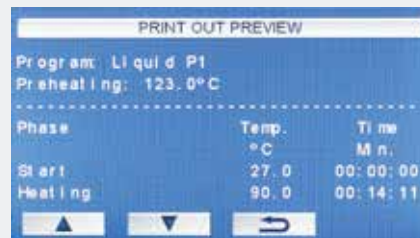
FULL TRACEABILITY AND REMOTE ACCESS

- Operating parameters can be tracked graphically against time
- Massive data storage with internal memory which stores the records of last 500 cycles detailed 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
- Possibility of PC Connection through USB / RS 232 port
- Ethernet port for remote access through internet by means of optional NuveCloser™ software
- NuveCloser™ allows access to operating parameters, memory ,failure history and other technical parameters
- Optional panel type printer to keep the records of the sterilization cycle



OLDER CYCLES				
NO	DATE	TIME	PROGRAM	ERROR
00001	02.10.15	15:33	Liquid P1	✓ ---
00002	02.10.15	10:50	Solid P4	✓ ---
00003	01.10.15	15:01	Solid P4	✓ ---
00004	01.10.15	14:03	Solid P4	✓ ---
00005	01.10.15	11:44	Solid P4	✓ ---

ERROR RECORDS		
NO	DATE	ERROR
00001	01.10.15	11:37 POWER FAILURE
00002	30.09.15	09:50 HIGH PRESSURE
00003	30.09.15	09:10 HIGH PRESSURE
00004	29.09.15	14:17 HIGH PRESSURE
00005	29.09.15	13:55 NO WATER



SAFETY OVER STANDARDS

- Password protected control system, service and calibration menu
- Lid safety system
 - Lid cannot be opened when the chamber is pressurized
 - Program cannot be operated if the lid is open
 - Lid can be opened when the liquid temperature is below 80°C after liquid sterilization
 - Lid can be opened when the chamber temperature is below 90°C after solid sterilization
- Comprehensive self-diagnostic system to provide the information regarding possible system malfunction. The self-diagnostic system warns user in case of:

- Broken temperature sensors
- Over temperature
- Heater failure
- Low temperature
- Overpressure
- Exhaust tank failure
- Lack of water
- High preheating temperature

- Colour of the display changes to red in case of any alarm condition along with an audible alarm
- Remote failure diagnostic by means of NüveCloser™ software
- Sending e-mails up to five e-mail addresses with the details of failure
- Optional AlerText™ SMS alarm system for ultimate security
- Safety valve against over pressure
- Manometer to follow the chamber pressure
- Chamber manufactured according to PED 2014/68 EC
- Validation port as standard



TECHNICAL SPECIFICATIONS

	NC 40M	NC 90M
Chamber Volume	40 litres	90 litres
Temperature Range	105°C - 135°C	
Control System	N-Smart™ Control System	
Display	4,3" Colourful LCD Display	
No of Preset Programs	2 For Liquids, 3 For Solids	
No of Free Programs	1 For Liquids, 1 For Solids	
Melting Program Temperature Range	60°C - 100°C	
Timer for Free Programs	1-300 minutes	
Timer for Melting Program	1-60 minutes	
Delayed Start Timer	Programmable With Real Date and Time	
Chamber Material	Stainless Steel	
No. of Baskets	2 pcs. (Ø 295x242 mm)	3 pcs. (Ø 360x242 mm)
Power Consumption	2.500 W	7.000 W
Power Supply	220 V 50/60 Hz.	400 V 50/60 Hz., 3 phases+N+G
Chamber Dimensions (Diameter x Depth) mm	Ø 320x520	Ø 396x750
External Dimensions (WxDxH) mm.	560x600x985	680x660x1050
Packing Dimensions (WxDxH) mm.	570x660x1200	730x760x1200
Net / Packed Weight kg.	80 / 91	113 / 134

Loading Capacity for NC 40M Erlenmeyer Flasks

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml
3x8 pcs.	2x4 pcs.	2x3 pcs.	1 pc.	1 pc.	1 pc.

Loading Capacity for NC 40M Schott-Duran Bottles

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml
3x12 pcs.	2x8 pcs.	2x5 pcs.	3 pc.	1 pc.	1 pc.

Loading Capacity for NC 90M Erlenmeyer Flasks

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml
4x12 pcs.	3x7 pcs.	3x4 pcs.	2x3 pcs.	2x1 pc.	1 pc.

Loading Capacity for NC 90M Schott-Duran Bottles

250 ml	500 ml	1000 ml	2000 ml	3000 ml	5000 ml	10000 ml
4x18 pcs.	3x11 pcs.	3x8 pcs.	2x4 pcs.	2x1 pc.	2x1 pc.	1 pc.

FACTORY FITTED OPTIONS

- NC XXMY Panel mounted thermal printer
 NC 90ME NuveLift™ to load/unload basket for NC 90M

OPTIONS

- A 08 191 AlerText™ GSM alarm module
 A 08 212 NuveCloser™ Software CD with 3 m. RS 232 cable

ACCESSORIES FOR OT 40L

- S 09 028 Basket (Height : 345 mm)
 S 09 027 Basket (Height : 242 mm)
 S 09 040 Basket (Height : 160 mm) (Unperforated)

ACCESSORIES FOR OT 90L

- S 09 034 Basket (Height : 360 mm)
 S 09 035 Basket (Height : 242 mm)
 S 09 041 Basket (Height : 170 mm)
 S 09 043 Basket (Height : 242 mm) (Special for NC 90ME)



NUVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

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