

Anexa 1. Sterilizator 110 L

Parametri ceruti	Parametri oferiti, Nuve FN 500P
Sterilizator 110 L Cod 270330 Descriere Sterilizator cu aer uscat destinat sterilizării instrumentelor medicale cu consctrucție interioară din oțel inox Parametrul Specificația Ventilație forțată, controlată electronic Construcție interioară oțel inox Construcție exterioară cu acoperire anticorozivă Regimuri de sterilizare programabile Protecție la supraîncălzire analogical digitală Alarmer acustică vizuală Diagnostic automat cu afișarea codului erorii Volumul 110l, ±10 l Camera sterilizatorului Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior Temperatura 50 - 200°C Divergență față de temperatura setată ≤ 1°C Abatere timp ≤ 1 min Timp încălzire până la temperatura setată ≤ 60 min Regim de sterilizare prestabilite 180°C, 60 min 160°C, 150 min 120°C, 45 min Rezoluția de programare 1°C Timpul de răcire ≤ 35 min, până la 75°C Deconectare de avariere la temperatura 205 - 235°C Tipul de funcționare fără întrerupere ≥ 8 ore Suport metalic pentru amplasarea sterilizatorului da, vopsit rezistent la soluțiile de dezinfectare Rafturi ≥ 3 Alimentare 200-240V, 50 Hz	Sterilizator 110 L Cod 270330 Descriere Sterilizator cu aer uscat destinat sterilizării instrumentelor medicale cu consctrucție interioară din oțel inox Parametrul Specificația Ventilație forțată, controlată electronic Construcție interioară oțel inox Construcție exterioară cu acoperire anticorozivă Regimuri de sterilizare programabile Protecție la supraîncălzire analogical digitală Alarmer acustică vizuală Diagnostic automat cu afișarea codului erorii Volumul 110l Camera sterilizatorului Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior Temperatura 5C peste ambient - 250°C Divergență față de temperatura setată 1°C Abatere timp 1 min Timp încălzire până la temperatura setată 60 min Regim de sterilizare prestabilite – NU, se seteaza de operator conform parametrilor necesari. Rezoluția de programare 1°C Timpul de răcire 35 min, până la 75°C Deconectare de avariere la temperatura 205 - 235°C Tipul de funcționare fără întrerupere ≥ 8 ore Suport metalic pentru amplasarea sterilizatorului da, vopsit rezistent la soluțiile de dezinfectare - NU Rafturi 3 Alimentare 200-240V, 50 Hz

Anexa 5. Autoclav 100 l cu încărcare orizontală

Parametri ceruti	Parametri oferiti, NUVE, NC 150
Autoclav 100 l cu încărcare orizontală (oțel inox) cu ciclu de vacuum Cod 270130 Descriere Sterilizatoare cu aburi cu ciclu de vacuum, cu încărcătură orizontală, utilizează aburi sub presiune care generează căldură umedă ce ajută la eliminarea microbilor viabili din dispozitive medicale non termic sensibile, inclusiv produse tolerante la căldură folosite pentru îngrijirea pacientului cu scopuri chirurgicale și generale. Construcția interioară este din oțel inox. Parametrul Specificația Încărcare orizontală Construcția interioară din oțel inox Exterior metalic galvanizat sau oțel inox. Securitate la supraîncălzire da Alarmer acustică, vizuală Durata sterilizării reglabilă da Regimuri de sterilizare presetate ≥ 5 programe Setarea de către utilizator a regimului de sterilizare dorit da Control electronic Microprocesor Sistem de blocare a ușii autoclavului care împiedică pornirea ciclului dacă este ușa deschisă da Ușa rămâne blocată până la scaderea sfârșitului procesului de sterilizare da Suprafața exterioară să nu se încălzească Imprimantă termică da Monitorizarea procesului pe ecran LCD sau afișaj LED Monitorizarea în timp real temperatura în camera de sterilizare presiune (prin manometru sau digital) vacuum (prin manometru sau digital) Ciclu de sterilizare Ciclu de presiune pozitivă Ciclu de vacuum Pre și post vacuum selectabil Sistem de uscare da Facilități de setare timp, temperatura eliberare automată a vaporilor, printare a rezultatelor racire rapidă Volum interior 100 l, ± 10 l Rafturi minim 2 buc Precizie timp de sterilizare ± 1 min. Gama de temperatură: 105 - 134 grade C Precizie temperatură $\pm 2^{\circ}\text{C}$ Autoclavul să fie conectat la conductele de apă și canalizare da "Să fie inclus sistem de filtrare a apei utilizate pentru procesul de sterilizare	Autoclav 100 l cu încărcare orizontală (oțel inox) cu ciclu de vacuum Cod 270130 Descriere Sterilizatoare cu aburi cu ciclu de vacuum, cu încărcătură orizontală, utilizează aburi sub presiune care generează căldură umedă ce ajută la eliminarea microbilor viabili din dispozitive medicale non termic sensibile, inclusiv produse tolerante la căldură folosite pentru îngrijirea pacientului cu scopuri chirurgicale și generale. Construcția interioară este din oțel inox. Parametrul Specificația Încărcare orizontală Construcția interioară din oțel inox Exterior metalic galvanizat sau oțel inox. Securitate la supraîncălzire da Alarmer acustică, vizuală Durata sterilizării reglabilă da Regimuri de sterilizare presetate 7 programe Setarea de către utilizator a regimului de sterilizare dorit da – 10 programe Control electronic Microprocesor Sistem de blocare a ușii autoclavului care împiedică pornirea ciclului dacă este ușa deschisă da Ușa rămâne blocată până la scaderea sfârșitului procesului de sterilizare da Suprafața exterioară nu se încălzește Imprimantă termică da Monitorizarea procesului pe ecran LCD sau afișaj LED Monitorizarea în timp real temperatura în camera de sterilizare presiune (prin manometru sau digital) vacuum (prin manometru sau digital) Ciclu de sterilizare Ciclu de presiune pozitivă Ciclu de vacuum Pre și post vacuum selectabil Sistem de uscare da Facilități de setare timp, temperatura eliberare automată a vaporilor, printare a rezultatelor racire rapidă Volum interior 150 l Rafturi - suport rafturi cu 6 rafturi (4 un. De 420x740 mm, 1 un. De 275x740 mm, 1 un. De 330x740 mm) Precizie timp de sterilizare 1 min. Gama de temperatură: 105 - 136 grade C Precizie temperatură $\pm 2^{\circ}\text{C}$ Autoclavul să fie conectat la conductele de apă și canalizare da Este inclus sistem de filtrare a apei utilizate pentru procesul de sterilizare

" da Înregistrator date da Tip date imprimate pe hirtie data timp temperatura presiune Alimentare Cerințe de alimentare la rețeaua electrică: 380V, 50 Hz	" da Înregistrator date da Tip date imprimate pe hirtie data timp temperatura presiune Alimentare Cerințe de alimentare la rețeaua electrică: 380V, 50 Hz
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NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

SARACALAR MAHALLESİ SARACALAR KÜMEEVLERİ NO:4/2
AKYURT – ANKARA – TURKEY

with a scope of

**DESIGN, MANUFACTURE, SALES AND AFTER SALES
SERVICES OF LABORATORY AND STERILIZATION EQUIPMENTS**

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

"Following elements of the standard are excluded"

"None"

ISO 9001:2015

Certificate No : M 8215
Initial Certification Date : 28 April 2010
Certification Date : 19 February 2019
Expiration Date : 18 February 2022



General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.

Please contact above numbers for detailed information.



CERTIFICATE

NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

SARACALAR MAHALLESİ SARACALAR KÜMEEVLERİ NO:4/2
AKYURT – ANKARA – TURKEY

with a scope of

DESIGN, MANUFACTURE AND AFTER SALES SERVICES OF LABORATORY AND STERILIZATION EQUIPMENTS

Medical devices - Quality management systems - Requirements for
regulatory purposes

"Following elements of the standard are excluded"

" 7.5.5 " " 7.5.7 " " 7.5.9.2 "

EN ISO 13485:2016

Certificate No : M 8216
Initial Certification Date : 28 April 2010
Certification Date : 19 February 2019
Expiration Date : 18 February 2022



Medical Device Q.M.S.
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO
YS-4DCF-FE40

General Manager

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Please contact above numbers for detailed information.*

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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HPI Verification Services Ltd.
The Manor House
Howbery Park, Wallingford
OX10 8BA, United Kingdom



FN SERIES

Dry Heat Sterilizers /Ovens

- Designed for the dry heat sterilization in medical, dentistry and veterinary applications
- Suitable for drying, warming and heating, heat treatment and long term stability tests in research and industrial laboratories
- Very homogeneous temperature distribution by natural air convection for FN 300/400/500 and by forced air ventilation for FN 400P/500P
- Anodic-oxidated aluminium chamber for FN 300/400/500 and stainless steel chamber for FN 400P/500P
- The door, pressing firmly and tightly on the chamber gasket to reduce temperature loss
- Adjustable outlet port for vapour exhaustion
- Reliable and accurate N-Prime™ programmable PID microprocessor control system
- User friendly control panel including large bright LED displays for temperature and time
- Easy programming with one button, just turn and push
- Password protected menu to secure the operation
- Programmable alarm limits
- Data recording on memory stick by means of USB port up to 125 days
- Programmable delayed start function
- Highly visible dual displays for temperature and time
- Adjustable independent safety thermostat which takes over control in case of any failure



N-prime

TECHNICAL SPECIFICATIONS

	FN 300	FN 400	FN 400P	FN 500	FN 500P
Temperature Range	Ambient Temp + 5°C / 250°C				
Temperature Sensor	Fe-Const				
Control System	N-Prime™ Programmable Microprocessor				
Temperature Set and Display Sensitivity	1°C				
Temperature Variation (100°C-150°C)	± 2°C				
Temperature Fluctuation	± 1°C				
Programmable Alarm Limits	± 2°C / 10°C				
Timer	1 minute – 99,9 hours + Hold Position				
Delayed Start Timer	1 minute – 99,9 hours				
Selectable Recording Frequency on Memory Stick	10 or 30 seconds, 1, 5, 30 or 60 minutes				
Useful Volume, litres	22	48	42	120	110
Number of Shelves (Standard/ Max.)	2/6	2/7	2/7	2/10	2/10
Internal Material	Anodic-oxidated Aluminium		Stainless Steel	Anodic-oxidated Aluminium	Stainless Steel
External Material	Epoxy - Polyester Powder Coated Steel				
Power Consumption	500 W	800 W	900 W	1600 W	1550 W
Power Supply	230 V, 50/60 Hz				
Internal Dimensions (WxDxH) mm.	300x240x300	420x320x360	420x280x360	500x480x500	500x445x500
External Dimensions (WxDxH) mm.	555x380x460	705x475x540	705x505x540	785x630x680	785x665x680
Packing Dimensions (WxDxH) mm.	640x470x640	790x570x750	790x580x760	870x740x860	870x740x860
Net / Packed Weight kg.	26 / 31	37 / 43	39 / 45	55 / 65	66 / 74

ACCESSORIES

R 01 014	Aluminium Shelf for FN 300
R 01 136	Mesh type shelf for FN 400
R 01 126	Mesh type shelf for FN 400P
R 01 135	Mesh type shelf for FN 500
R 01 111	Mesh type shelf for FN 500P
K 23 031	Shelf carrier for FN 300
K 23 047	Shelf carrier for FN 400
K 23 048	Shelf carrier for FN 400P
K 23 046	Shelf carrier for FN 500
K 23 040	Shelf carrier for FN 500P

Note: 2 pcs. shelf carrier should be ordered for each shelf



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ISO 9001: 2008

ISO 13485: 2003





NC 150/150D

Horizontal Steam Sterilizers



N-s22art

NC 150/150D

HORIZONTAL STEAM STERILIZERS

NC 150/150D Horizontal Steam Sterilizer is designed the sterilization of textile, wrapped or packed materials, glass and liquid in operating theatres and laboratories of hospitals; dentistry; biology, veterinary and agriculture departments of universities; microbiology and quality control laboratories of industry such as food.

With its double doors, NC 150D is ideal solution for the small sterilization centers which have divided as clean and dirty areas.

VERSATILE OPERATING SYSTEM

- Integrated steam generator for fast production of steam
- Maintenance-free diaphragm type powerful vacuum pump
- Fractionated pre-vacuum to eliminate all air bubbles and achieve successful steam penetration
- Fractionated post-vacuum for efficient drying of the samples
- Air driven gasket with internal compressor
- Pressure measurement of gasket
- Connected directly to water supply through siliphos filter supplied.
- Delivered with shelf carrier and shelves
- 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





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 to use
- Password protected menu to secure run parameters and data
- Easy to understand 5 Languages: Turkish, English, French, Russian, Spanish
- Icons make the operations easier for immediate understanding

EASY STERILIZATION

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

Resistant textile	136°C	20 minutes
Wrapped porous	134°C	20 minutes
Prion	134°C	20 minutes
Quick, unwrapped	134°C	4 minutes
Resistant rubber	121°C	20 minutes
Sensitive material	121°C	20 minutes
Gravity	121°C	20 minutes

- Programmable ten free programs:

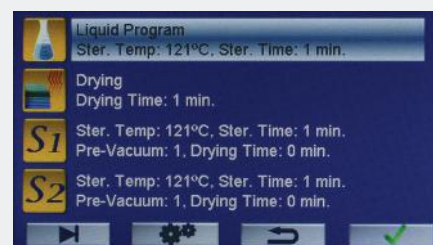
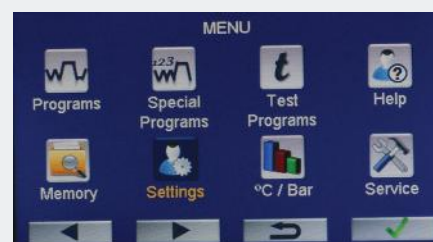
Temperature : 105°C - 136°C

Sterilization time: 1 - 99 minutes

No. of pre vacuum: 1 - 4

Drying time: 1-30 minutes

- Two special programs for liquid sterilization and drying
- Programmable pre-heating

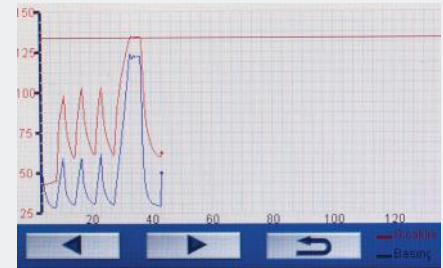


TEST PROGRAMS

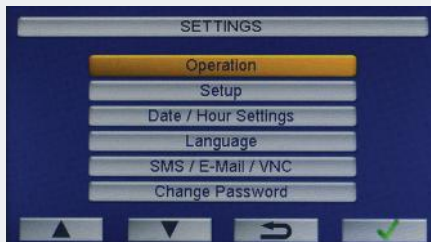
- Vacuum leakage test and Bowie & Dick test

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 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 printer connection through USB / RS 232 port for printing the cycles in the memory or connection to PC
- Ethernet port for remote access through internet by means of optional NüveCloser™ software
- NüveCloser™ allows to access operating parameters, memory ,failure history and other technical parameters
- Panel type printer to keep the records of the sterilization cycle



OLDER CYCLES				
NO	DATE	TIME	PROGRAM	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	---

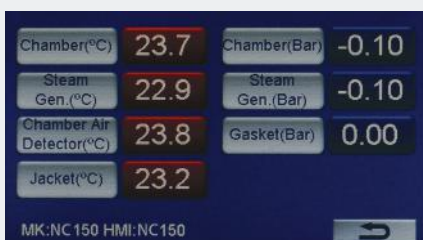
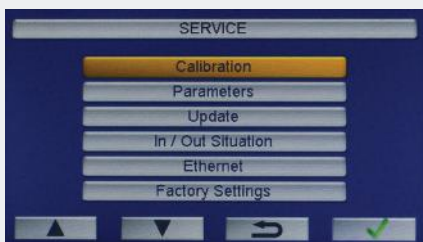
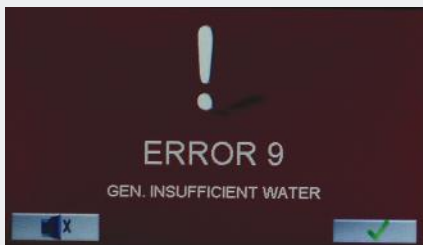


PROCESS EVALUATION AND SELF DIAGNOSTIC SYSTEM

- Compare the preset values with operating parameters using the process evaluation system
- When the operating parameters do not match the preset values, the sterilization cycle is cancelled and the user is warned
- Comprehensive self-diagnostic system for 19 possible failures such as power failure, heater failure, low water level, high pressure and temperature, sensor failure

SAFETY OVER STANDARDS

- Password protected control system, service and calibration menu
- Lid safety system
- Colour of the display changes to red in case of any alarm condition along with an audible alarm
- Reminder for gasket and filter replacement
- 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
- HEPA filter at air intake line
- Certified chamber and generator according to PED 2014/68
- Validation port as standard



TECHNICAL SPECIFICATIONS

	NC 150	NC 150D
Chamber Volume, litres	170	150
Sterilization Temperature	105-136°C	
No of Preset Programs	7	
No of Free Programs	10	
Special Programs	Liquid Sterilization and Drying	
Test Programs	Vacuum Leakage, Bowie & Dick	
Minimum Vacuum Level	200 mbar	
Control System	N-Smart™ Control System	
Display	4,3" Colourful LCD Display	
Internal Material	Stainless Steel	
External Material	Stainless Steel and Epoxy Polyester Powder Coated Stainless Steel	
Standard Accessories	Shelf Carrier and 6 Shelves (4 pcs. 420x740 mm, 1 pc. 275x740 mm, 1pc. 330x740 mm)	
Power Consumption	11,500 W	
Power Supply	400 V 50/60 Hz, 3 phases + N + G	
Chamber Dimensions (DiaxD) mm.	Ø 496x880	Ø 496x777
External Dimensions (WxDxH) mm.	670x1010x1580	670x1030x1580
Packing Dimensions	880x1300x1780	
Net / Packed Weight kg.	300 / 390	342 / 402

FACTORY FITTED OPTION

- A 08 209 Loading cart for shelf and STU carrier
A 08 210 STU carrier and 1 pc. STU

OPTIONS

- A 08 191 AlerText™ GSM alarm module
A 08 213 NuveCloser™ Software CD with 3 m. RS 232 cable



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ISO 9001: 2008
ISO 13485: 2012

