

EC DECLARATION OF CONFORMITY

We, NÜVE Sanayi Malzemeleri İmalat ve Ticaret A.Ş.
Saracalar Mah. Saracalar Kümeevleri No: 4/2
Akyurt 06750 Ankara / TURKEY

herewith declare that the following described product meets the provisions of the Council Directive 93/42/EEC (2007/47/EC) for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

PRODUCT:

DRY AIR STERILIZER

MODEL:

FN 032 – FN 055 – FN 120

CLASSIFICATION:

IIB, Annex IX - RULE 15

GMDN:

35364

CONFORMITY ASSESMENT ROUTE:

MDD 93/42/EEC (2007/47/EC), ANNEX II.3

**APPLICABLE HARMONISED
STANDARDS:**

EN 60601-1	EN 62366
EN ISO 15223-1	EN 60601-1-2
EN 62304	EN ISO 14971
EN 60601-1-6	EN 61000-6-3

NOTIFIED BODY:

**KİWA MEYER
BELGELENDİRME HİZMETLERİ A.Ş.
(İTOSB) İstanbul Tuzla Organize Sanayi
Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul
TURKEY**

CERTIFICATE NUMBER:

1984-MDD-10-030

DATE OF ISSUE:

May 29, 2015

SIGNATURE:



**Beril İZGİN
General Manager**

CE
1984



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
- Air jacketed heating system for highly precise and constant temperatures
- Very homogeneous temperature distribution by natural air convection
- Triple insulation consisting of glass wool, aluminium layer and air gap for high efficiency
- Stainless steel chamber which has high resistance to most of the chemicals
- 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 032	FN 055	FN 120
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 @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	32	55	120
Number of Shelves (Standard/ Max.)	2/6	2/7	2/10
Internal Material	Stainless Steel		
External Material	Epoxy - Polyester Powder Coated Steel		
Power Consumption	700 W	1400 W	1600 W
Power Supply	230 V, 50/60 Hz		
Internal Dimensions (WxDxH) mm	330x300x335	410x370x360	500x480x500
External Dimensions (WxDxH) mm	565x495x680	645x565x710	730x670x850
Packing Dimensions (WxDxH) mm	650x590x890	740x640x870	830x760x1050
Net / Packed Weight kg.	36 / 42	47 / 54	62 / 72

FACTORY FITTED OPTIONS

FN XXX N N-Smart™ Control system

OPTIONS FOR N-Smart™ CONTROL SYSTEM

A 08 190 NüveCom™ communication unit
A 08 191 NüveCloser™ Software CD with 3 m. RS 232 cable (should be ordered with A 08 190)
A 08 195 AlerText™ GSM alarm module (should be ordered with A 08 190)

ACCESSORIES

R 01 133 Mesh type shelf for FN 032
R 01 127 Mesh type shelf for FN 055
R 01 131 Mesh type shelf for FN 120
K 23 049 Shelf carrier for FN 032
K 23 048 Shelf carrier for FN 055
K 23 040 Shelf carrier for FN 120

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



NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

Saracalar Mah. Saracalar Kümevleri No: 4/2 Akyurt 06750 ANKARA / TURKEY t. +90 312 399 28 30 f. +90 312 399 21 97
nuve.com.tr sales@nuve.com.tr

ISO 9001: 2008
ISO 13485: 2003



Anexa 15. Sterilizator 110 L (270330)

Nuve FN 120

Parametri ceruti	Parametri oferiti
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 $\leq 1^{\circ}\text{C}$ 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 120 l Camera sterilizatorului Să mențină steril instrumentele în interiorul camerei, să nu fie orificii cu acces direct la exterior Temperatura 5 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 catre operator la sterilizare Rezoluția de programare 1°C Timpul de răcire 35 min, până la 75°C Deconectare de avariere la temperatura la temperaturi ce depasesc cea setarta cu $2/10^{\circ}\text{C}$ Tipul de funcționare fără întrerupere 9 ore Suport metalic pentru amplasarea sterilizatorului da, vopsit rezistent la soluțiile de dezinfectare - NU Rafturi 3 Alimentare 200-240V, 50 Hz



CERTIFICATE

NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET ANONİM ŞİRKETİ

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

LABORATUVAR VE STERİLİZASYON CİHAZLARI TASARIMI,
ÜRETİMİ, SATIŞ VE SATIŞ SONRASI SERVİS HİZMETLERİ

kapsamında

ISO 9001:2015

Uluslararası kalite sistem standardına uygun
bir kalite yönetim sistem kurmuştur.

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"

"Hariç tutma yoktur."

Sertifika No	: M 8215
İlk Belgelendirme Tarihi	: 28 Nisan 2010
Sertifika Tarihi	: 19 Şubat 2019
Son Geçerlilik Tarihi	: 18 Şubat 2022



Genel Müdür

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Türkiye
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Sertifikalar periyodik ara denetimlerin başarılı ile tamamlanması kaydıyla geçerlidir.
Detaylı bilgi için yukarıdaki numaralara başvurulabilir.

Sertifika Son Güncelleme Tarihi : 19 Şubat 2019 - R 05



TÜRKAK BDS NO
YS-4AF4-45D4

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



TÜRKAK BDS NO
YS-4AF4-45D4



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 – TÜRKİYE

LABORATUVAR VE STERİLİZASYON CİHAZLARI
TASARIMI, ÜRETİMİ VE SATIŞ SONRASI SERVİS HİZMETLERİ

kapsamında

EN ISO 13485:2016

Tıbbi Cihazlar - Kalite yönetim sistemleri – Düzenleyici amaçlar için gereklilikler

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"

" 7.5.5 " " 7.5.7 " " 7.5.9.2 "

Sertifika No	: M 8216
İlk Belgelendirme Tarihi	: 28 Nisan 2010
Sertifika Tarihi	: 19 Şubat 2019
Son Geçerlilik Tarihi	: 18 Şubat 2022



Medikal Cihazlar K.Y.S.
TS EN ISO/IEC 17021-1

AB-0006-YS



TÜRKAK BDS NO
YS-4DCF-FE40

Genel Müdür

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Türkiye
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

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Detaylı bilgi için yukarıdaki numaralara başvurulabilir.

Sertifika Son Güncelleme Tarihi : 19 Şubat 2019 - R 04



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

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.*

Last Modified: 19 February 2019 - R 04