

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:

FREEZER (-86°C)

MODEL:

DF 290 / DF 490 / DF 590

CLASSIFICATION:

IIA, Annex IX - RULE 2

GMDN:

35704

CONFORMITY ASSESMENT ROUTE:

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

APPLICABLE HARMONISED STANDARDS:

EN 60601-1: 2006 EN 62304: 2006
EN 60601-1-2: 2015 EN 62366-1: 2015
EN 60601-1-6: 2010 EN 61000-6-3: 2007

NOTIFIED BODY:

KİWA 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:

February 19, 2019

SIGNATURE:



Beril İZGİN
General Manager

CE
1984

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



FR/DF SERIES

Freezers and ULT Freezers



N-start

FR / DF SERIES

Freezers and ULT Freezers

DirectFREEZE™

FAST, CONTACT FREEZING

With its cooling coils entirely situated inside the chamber, unlike other brands whose coils are outside the walls of the chamber, 100% of the cooling power is available to freeze the samples and keep them frozen. The placement of the coils throughout the storage volume provides unbeatable homogeneity, so that all samples are maintained under identical conditions, ensuring that evaluations done using these samples can be compared with confidence.

Since sample containers can be placed directly on the shelves containing the cooling coils, heat is removed by conduction that is many times more efficient than relying on conventional convection through the air.

- Freezing through the cooling coils located inside the shelves
- Faster freezing than conventional freezers that use only convection
- All cooling power is used for the freezing of the samples, not the body
- Excellent temperature stability and homogeneity with direct cooling inside the chamber
- Fast and efficient freezing since the samples are directly in touch with the cooling source
- Optimized recovery time after a door opening



TECHNICAL SPECIFICATIONS

	FR 290	FR 490	FR 590	DF 290	DF 490	DF 590
Minimum Temperature	-41 °C*			-86 °C**		
Freezing System	DirectFREEZE™ cooling coils in shelves inside the chamber					
Control System	N-Smart™					
Display	4,3" Colourful LCD Display					
Chamber Configuration	3 independent compartments with insulated inner doors	4 independent compartments with insulated inner doors		3 independent compartments with insulated inner doors	4 independent compartments with insulated inner doors	
Temperature Homogeneity	±3°C***					
Temperature Stability	±0.5°C***					
Temperature Alarm Range	Set point +5°C / +10°C			Set point +5°C / +25°C		
Remote and Central Alarm Contact	For all alarm conditions					
Alarm Back-up	12-hour with automatically recharged battery					
Insulation	High density injected polyurethane					
Internal Material	Stainless steel					
External Material	Epoxy-polyester powder coated stainless steel					
Chamber Volume, Litres	260 (Up to 18,000 cryotubes in cryoboxes)	455 (Up to 32,000 cryotubes in cryoboxes)	560 (Up to 40,000 cryotubes in cryoboxes)	260 (Up to 18,000 cryotubes in cryoboxes)	455 (Up to 32,000 cryotubes in cryoboxes)	560 (Up to 40,000 cryotubes in cryoboxes)
Power Consumption	900 W	900 W	900 W	1600 W	1600 W	1600 W
Power Supply	230 V, 50 Hz					
Internal Dimensions (WxDxH) mm	420 x 630 x 995	555 x 630 x 1320	555 x 770 x 1320	420 x 630 x 995	555 x 630 x 1320	555 x 770 x 1320
External Dimensions (WxDxH) mm	680 x 975 x 1630	820x 975 x 2010	820 x 1120 x 2010	680 x 975 x 1715	820x 975 x 2035	820 x 1120 x 2035
Packing Dimensions (WxDxH) mm	1030x1020x1950	1030x1020x2140	1310x970x2230	1030x1020x1950	1030x1020x2140	1310x970x2230
Net / Packed Weight kg.	210 / 245	255 / 295	282 / 414	245 / 272	285 / 330	312 / 444

*At 30°C ambient **At 20°C ambient *** Measured from the samples

FACTORY FITTED OPTIONS

DF XXX Y Weekly temperature chart recorder 0°C / -100°C FR XXX Y Weekly temperature chart recorder 0°C / -50°C

OPTIONS AND ACCESSORIES

A 08 191	AlerText™ GSM alarm module		
K 13 009	NuveWarn™ remote alarm system with 10 m cable		
A 08 195	NuveCloser™ Software CD with 3 m. RS 232 cable	A 08 200	Rack for 135x135x50 mm PP cryoboxes (Rack capacity: 25 boxes) (DF/FR 590)
A 08 135	CO ₂ back up unit	A 08 138	PP Cryobox 133x133x52 mm capacity 9 x 9 tubes
A 08 203	Rack with two drawers (DF/FR 290)	A 08 165	PP Cryobox 133x133x75 mm capacity 9 x 9 tubes
A 08 204	Rack with three drawers (DF/FR 290)	A 08 171	Cryobox 133x133x50 mm
A 08 152	Rack with two drawers (DF/FR 490)	A 08 172	10x10 Divider for up to Ø 12 mm tubes. Divider height: 30 mm.
A 08 150	Rack with three drawers (DF/FR 490)	A 08 173	9x9 Divider for up to Ø 13.6 mm tubes. Divider height: 30 mm
A 08 196	Rack with two drawers (DF 590)	A 08 155	Cryobox 135x135 mm Height 75 mm
A 08 197	Rack with three drawers (DF 590)	A 08 158	10x10 Divider for up to Ø 12 mm tubes. Divider height: 65 mm.
A 08 137	Rack for 135x135x50 mm PP cryoboxes (Rack capacity: 20 boxes) (DF-FR 290/490)	A 08 159	9x9 Divider for up to Ø 13.6 mm tubes. Divider height: 65 mm.
A 08 180	Rack for 135x135x50 mm cryoboxes (Rack capacity: 20 boxes) (DF-FR 290/490)	A 08 160	Diagram paper for chart recorder 0°C / -100°C (Pack of 100)
A 08 151	Rack for 135x135x75 mm cryoboxes (Rack capacity: 16 boxes) (DF-FR 290/490)	A 08 070	Pen for chart recorder
A 08 198	Rack for 133x133x75 mm cryoboxes (Rack capacity: 20 boxes) (DF/FR 590)		
A 08 199	Rack for 137x137x50 mm cryoboxes (Rack capacity: 25 boxes) (DF/FR 590)		

When choosing dividers, take into account the diameter of the cap on the cryotube. Other types of cryoboxes and dividers can be supplied on request.

Contact us for custom storage requirements.



NUVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

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ISO 9001: 2008
ISO 13485: 2003



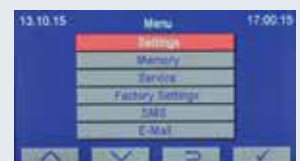
OPTIMIZED FUNCTIONALITY AND RUGGED DESIGN

A cooling coil is at the top (naturally the warmest part) of every chamber to reduce temperature gradients. Thick shelves, incorporating the coils, block the gaps between inner doors, limiting air exchange and cooling any air that enters in before it reaches the samples. In the long term, snow is created instead of ice because of the maintenance of the cold air in the sealed compartments.

- Independent compartments with insulated doors for decreasing air entry
- Minimized air exchange on opening reduces ice build-up and protects samples
- Compartment dimensions match commonly used cryoboxes
- Washable air filter for simple maintenance and top performance
- Perfect airtightness with soft gasket
- Heated contact surface of gasket to virtually eliminate icing-up
- Chamber made of stainless steel for long life and shelves made of aluminium for faster heat transfer
- Epoxy polyester powder coated stainless steel outer body
- Foamed-in-place high density polyurethane insulation
- Easy to move with their castors

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 make the operations easier for immediate understanding



OPTIMAL SOLUTIONS FOR SAMPLE STORAGE

Our racking system design has been optimized to accommodate the maximum number of samples in the available space, optimizing return on your investment and minimizing the floor space required for storage. Our standard series responds to the majority of requirements and our custom manufacturing service ensures that we have an answer to your special needs

- Racks for most commonly used cryoboxes and storage vials
- Drawers for the storage of different types of samples such as plasma bags, flasks
- Custom made racks and drawers are available

RACKS FOR CRYOBXES

Freezer Model	Code	Box Dimensions (mm) and Type	No. of cryoboxes per racks	No. of rack per freezer	Total no. of cryoboxes per freezer	Max. total tube capacity
DF/FR 290	A 08 137	13x135x50 mm PP Box	20	9	180	18,000
	A 08 180	13x135x50 mm Cardboard Box	20	9	180	18,000
	A 08 151	13x135x75 mm Cardboard/PP Box	16	9	144	14,400
DF/FR 490	A 08 137	13x135x50 mm PP Box	20	16	320	32,000
	A 08 180	13x135x50 mm Cardboard Box	20	16	320	32,000
	A 08 151	13x135x75 mm Cardboard/PP Box	16	16	256	25,600
DF/FR 590	A 08 200	13x135x50 mm PP Box	25	16	400	40,000
	A 08 199	13x135x50 mm Cardboard Box	25	16	400	40,000
	A 08 198	13x135x75 mm Cardboard/PP Box	20	16	320	32,000

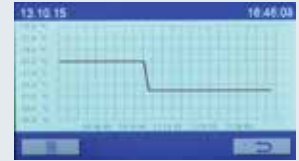
DRAWERS

Freezer Model	Code	Rack Type	Drawer Dimensions (mm)	No. of rack per freezer	Total no. of drawers per freezer
DF/FR 290	A 08 203	Rack with two drawers	192x530x143	6	12
	A 08 204	Rack with three drawers	192x530x95	6	18
DF/FR 490	A 08 152	Rack with two drawers	260x530x143	8	16
	A 08 150	Rack with three drawers	260x530x95	8	24
DF/FR 590	A 08 196	Rack with two drawers	260x665x143	8	16
	A 08 197	Rack with three drawers	260x665x95	8	24



FULL TRACEABILITY AND REMOTE ACCESS

- Operating parameters tracked digitally or graphically against time
- Massive data storage with internal memory which stores records up to ten years with one hour intervals, digitally and graphically
- Selectable recording frequency for storing temperature data on memory stick: 10 or 30 seconds, 1, 5, 30 or 60 minutes
- PC connection through USB 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 battery operated weekly chart recorder with key lock providing permanent record of storage conditions with its high resolution



Time	Temperature	Time	Temperature
00:00	-78	01:00	-79
02:00	-80	03:00	-80
04:00	-81	05:00	-81
06:00	-81	07:00	-81



MAXIMUM SAFETY FOR HIGH VALUE SAMPLES

NUVE knows that the contents of a low temperature freezer are usually worth many times the cost of the freezer itself. That is why we have incorporated numerous features dedicated to security.

No need to worry what is happening in your absence. A full set of alarm are built in and various optional features will inform you instantly and wherever you are.



- Password protected control system

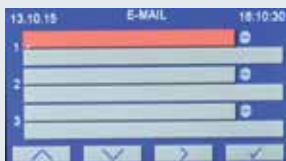
- Door with key lock



- Key operated mains power switch to protect the samples

- Audible and visual alarm system for :

- High temperature conditions - Power failure - Open door
- Temperature sensor failure - Refrigeration failure - Clogged air filter



- Colour of the display changes to red in case of any alarm condition

- Automatically rechargeable battery for alarm system

- Display of the actual temperature even at power failure

- Memory for the last 50 failures for easy servicing

- Remote failure diagnostics by means of NuveCloser™ software

- Sending e-mails up to five e-mail addresses with the details of failure

- Standard remote and central alarm ports



- Optional battery-operated 7-day chart recorder

- Optional AlerText™ SMS alarm system for ultimate security

- Optional NuveWarn™ remote alarm system

- Optional CO2 back-up system extends protection in case of failure (DF only)

