

Anexa 8 Frigider pentru produse sanguine cu usa transparentă 650-850 Litri

Nuve KN 294

Parametri ceruti	Parametri oferiti
<p>"Frigider pentru produse sanguine cu usa transparentă 650-850L</p> <p>Descriere Frigidere proiectate pentru a stoca produse sanguine la temperaturi de obicei între 2 și 8 grade C.</p> <p>Aceste frigidere constau în mod obișnuit dintr-o cameră cu un interior rezistent la coroziune (oțel inoxidabil de obicei), minimizarea riscului de alterare, contaminare și / sau coroziune a conținutului.</p> <p>Parametrul Specificația</p> <p>Configurație mobil</p> <p>Capacitatea 650-850 l</p> <p>Număr de rafturi 5 - 8</p> <p>Ușă Număr 1</p> <p>Descriere transparentă</p> <p>Mecanism blocare cu cheie</p> <p>Roți da</p> <p>Frâne da</p> <p>Lumină interior da</p> <p>Construcție interioară inox medical sau materiale anti-bacterial prevazut pentru prelucarare</p> <p>Construcție exterioară cu acoperire anticorozivă</p> <p>Afisaj temperatură digital</p> <p>Alarme acustică vizuală</p> <p>Răcire ventilată</p> <p>Înregistrator de temperatură grafic timp de 7 zile</p> <p>Temperatura reglabilă - +2 ... +8 °C</p> <p>stabilitate - ± 1,5 °C</p> <p>rezoluție - 1 °C</p> <p>Alimentare 220 V, 50 Hz</p> <p>Zgomot < 50 dB"</p>	<p>"Frigider pentru produse sanguine cu usa transparentă 630L</p> <p>Descriere Frigidere proiectate pentru a stoca produse sanguine la temperaturi de obicei între 2 și 8 grade C.</p> <p>Aceste frigidere constau dintr-o cameră cu un interior rezistent la coroziune (oțel inoxidabil de obicei), minimizarea riscului de alterare, contaminare și / sau coroziune a conținutului.</p> <p>Parametrul Specificația</p> <p>Configurație mobil</p> <p>Capacitatea 630 l (294 pungi de sange)</p> <p>Număr de rafturi 6</p> <p>Ușă Număr 1</p> <p>Descriere transparentă</p> <p>Mecanism blocare cu cheie</p> <p>Roți da</p> <p>Frâne da</p> <p>Lumină interior da</p> <p>Construcție interioară inox medical sau materiale anti-bacterial prevazut pentru prelucarare</p> <p>Construcție exterioară cu acoperire anticorozivă</p> <p>Afisaj temperatură digital</p> <p>Alarme acustică vizuală</p> <p>Răcire ventilată</p> <p>Înregistrator de temperatură grafic timp de 7 zile</p> <p>Temperatura reglabilă - +2 ... +8 °C</p> <p>stabilitate - ± 1,5 °C</p> <p>rezoluție - 1 °C</p> <p>Alimentare 220 V, 50 Hz</p> <p>Zgomot 59 dB"</p>

Configuratie oferita:

- A. Nuve KN 294
- B. KN XXX Y Înregistrator de temperatură pe suport de hartie(Battery operated 7-day chart recorder)

Anexa 19 Biosan PST-60HL-4 , Plate Shaker-Thermostat

Parametri ceruti	Parametri ofertati
Gama de setare a temperaturii: +25°C ... +60°C Gama de control al vitezei: 250–1200 rpm (increment 10 rpm) Setarea timpului digital : 1 min–96 ore (increment 1 min) Temporizator semnal sonor : Da Numărul de plăci (96 godeuri) : 4	Gama de setare a temperaturii: +25°C ... +60°C Gama de control al vitezei: 250–1200 rpm (increment 10 rpm) Setarea timpului digital : 1 min–96 ore (increment 1 min) Temporizator semnal sonor : Da Numărul de plăci (96 godeuri) : 4



CERTIFICATE

**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

A handwritten signature in black ink, appearing to read "M. Alp Uzun".

19 February 2019, Istanbul, Turkey

Head of Notified Body



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

General Manager



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

AB-0006-YS



TÜRKAK BDS NO
YS-4DCF-FE40

Kiwa Certification Services Inc.

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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.



KN SERIES

Blood Bank Refrigerators



N-Smart



KN Series Blood Bank Refrigerators are designed for the storage of whole blood and blood components providing maximum protection and traceability for the stored products by means of their advanced technology and N-Smart™ control system.

ROBUST BODY

- Easy to clean stainless steel chamber
- Humidity and solvent resistant epoxy-polyester powder coated stainless steel outer body
- Large triple glass door window for perfect insulation and easy observation of blood bags
- Antifogging inner glass to avoid condensation and outer glass blocks UV light
- Prevention of air leakage from the chamber and ambient air ingress with magnetic gasket
- Vibration free operation

OPTIMIZED FUNCTIONALITY

- Stainless steel drawers with perforated bottom for proper air circulation
- Easily drawn drawers
- Plexiglass cover in the front of the drawers to prevent warm air entry and easy control of the blood bags
- Plexiglass separators holding the blood bags in angled position for easy label reading
- Chamber illumination with switch control
- Temperature calibration port as standard

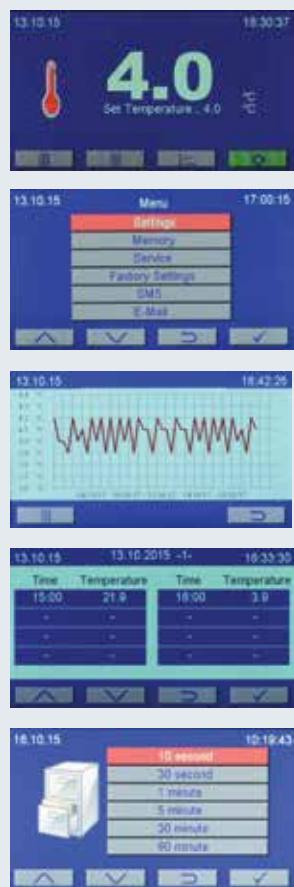
PERFECT TEMPERATURE CONTROL

- Excellent temperature uniformity and stability at all drawer levels with powerful air circulation system
- Quick recovery after door opening by means of directional air flow
- Full automatic defrost system to maintain refrigeration efficiency
- Temperature measurement from a bottle containing a liquid which has similar thermal specifications as blood for controlling and monitoring the real temperature of the stored blood
- Efficient insulation by means of high density injected polyurethane



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



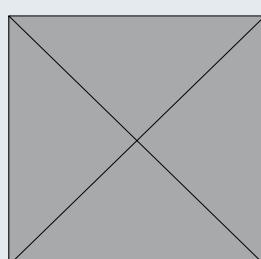
FULL TRACEABILITY AND REMOTE ACCESS

- Operating parameters tracked digitally or graphically against time
- Massive data storage with internal memory which stores the records up to ten years with one hour intervals, digitally and graphically
- Selectable recording frequency for storing the 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 to access 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



SAFETY OVER STANDARDS

- Password protected control system
- Door with key lock
- Key operated mains power switch to protect the samples
- Audible and visual alarm system for :
 - High and low temperature conditions
 - Temperature sensor failure
 - Power failure
 - Open door
- Color 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 AlerText™ SMS alarm system for ultimate security
- Optional NuveWarn™ remote alarm system



TECHNICAL SPECIFICATIONS

	KN 72	KN 120	KN 294	KN 504
Nominal Storage Capacity, Blood Bags*	72 pcs.	120 pcs.	294 pcs.	504 pcs.
Chamber Capacity, Liters	200	303	630	1090
Display		4,3" Colorful LCD Display		
Control System		N-Smart™ Control System		
Temperature Range		0°C / 10°C		
Temperature Set And Display Sensitivity		0,1°C		
Temperature Sensor		Pt 100		
Temperature Uniformity @+4°C		±1°C		±1,5°C
Temperature Alarm		Set Temperature ±2°C / Audible and Visual		
Power Failure Alarm		Audible and Visual		
Door Alarm		Audible and Visual		
Remote Alarm Contact		For All Alarm Conditions		
Alarm Back-Up		Automatic Re-chargable Battery For 12-Hours		
Door		Insulated Steel Frame With Triple Glass Window and Key Lock		
No. of Drawers	3	5	6	12
Insulation		High Density Injected Polyurethane		
Internal Material		Stainless Steel		
External Material		Epoxy-Polyester Powder Coated Stainless Steel		
Power Consumption	330 W	330 W	800 W	1000 W
Power Supply		230 V, 50/60 Hz		
Internal Dimensions (WxDxH) mm	480x545x770	480x545x1170	735x635x1350	1274x635x1350
External Dimensions (WxDxH) mm	610x805x1255	610x805x1855	917x895x1985	1544x900x1985
Packing Dimensions (WxDxH) mm	700x860x1430	700x860x2040	1030x1020x2140	1740x1050x2180
Net / Packed Weight kg.	120 / 136	180 / 205	275 / 305	445 / 680

* Nominal storage capacity may vary according to the loading method and preferences.

FACTORY FITTED OPTIONS

KN XXX Y Battery operated 7-day chart recorder

OPTIONS

- A 08 195 NuveCloser™ Software CD with 3 m. RS 232 cable
- A 08 191 AlerText™ GSM alarm module
- K 13 009 NuveWarn™ remote alarm system with 10 m cable
- A 08 070 Pen for chart recorder
- A 08 073 Diagram paper for chart recorder (pack of 100)



NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

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ISO 9001: 2008
 ISO 13485: 2003

PST-60HL-4, Plate Shaker-Thermostat



■ DESCRIPTION

Plate Thermo-Shakers are designed for shaking and thermostating 4 standard 96-well microplates.

A multisystem principle, used in design of the Thermo-Shaker, allows operating it as 3 independent devices:

- Incubator;
- Microplate shaker;
- Thermo-Shaker.

A distinctive feature of Biosan Plate Thermo-Shakers is the patented by the company Two-Side Microplates Heating, which allows to achieve full correspondence of the set and actual temperature in the microplate wells.

Thermo-shaker provides heating up to 60°C, which is sufficient for carrying out ELISA tests.

Plate Shaker-Thermostat provides:

- Soft or intensive sample shaking
- Rotation speed regulation, stabilization and indication
- Even rotation amplitude throughout the Thermo-Shaker platform
- Required operation time setting and indication
- Automatic stopping of the platform movement after expiration of the set time
- Setting and indication of the required temperature on the platform
- Automatic fault diagnostics (temperature sensor, platform heating, lid heating etc.)
- Spring clamps

Application fields:

- Cytochemistry — for in situ reactions
- Immunochemistry — for immunofermentative reactions
- Biochemistry — for enzyme and protein analysis
- Molecular biology — for micro array analysis

Temperature Calibration Function

With the help of the temperature calibration function the user can calibrate the unit approx. $\pm 6\%$ of the selected temperature to compensate differences in the thermal behaviour of plates from different manufacturers.



■ CAT. NUMBER

BS-010128-AAI	230VAC 50/60Hz Euro plug
BS-010128-AAQ	230VAC 50/60Hz UK plug
BS-010128-AA4	230VAC 50/60Hz AU plug
BS-010128-AAJ	100VAC 50/60Hz US plug, 120VAC 60Hz US plug
BS-010128-AK	IQ OQ document
BS-010128-BK	PQ document

SPECIFICATIONS

Temperature setting range	+25°C ... +60°C
Temperature control range	+5°C above ambient ... +60°C
Temperature setting resolution	0.1°C
Temperature stability	±0.1°C
Temperature uniformity at +37°C	±0.25°C
Heating	Patented two-side microplate heating
Speed control range	250–1200 rpm (increment 10 rpm)
Digital time setting	1 min–96 hrs / non-stop* (increment 1 min)
Timer sound signal	+
Orbit	2 mm
Display	LCD, 16 x 2 signs
Max. height of microtest plate	18 mm
Number of microtest plates	4
Platform dimensions (w x d)	290 x 210 mm
Overall dimensions (W×D×H)	380 x 390 x 140 mm
Weight	8.8 kg
Input current/power consumption	12 V DC, 4.15 A / 50 W
External power supply	Input AC 100–240 V; 50/60 Hz; Output DC 12 V
* Timer range can be reprogrammed on customers demand	+

EU Declaration of Conformity

Unit type	Thermo-Shakers
Models	TS-100, TS-100C, TS-100C Smart, TS-DW, PST-60HL, PST-60HL-4, PST-100HL
Serial number	14 digits styled XXXXXXXYMMZZZ, where XXXXXX is model code, YY and MM – year and month of production, ZZZZ – unit number.
Manufacturer	SIA BIOSAN Latvia, LV-1067, Riga, Ratsupites str. 7/2

The objects of the declaration described above is in conformity with the following relevant Union harmonization legislations:

LVD 2014/35/EU	LVS EN 61010-1:2011 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements. LVS EN 61010-2-010:2015 Particular requirements for laboratory equipment for the heating of materials. LVS EN 61010-2-051:2015 Particular requirements for laboratory equipment for mixing and stirring.
EMC 2014/30/EU	LVS EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
RoHS3 2015/863/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
WEEE 2012/19/EU	Directive on waste electrical and electronic equipment.

I declare that the Declaration of Conformity is issued under sole responsibility of the manufacturer and belongs to the above-mentioned objects of the declaration.

Svetlana Bankovska
Managing director


Signature

07.02.2020.

Date