

EC CERTIFICATE AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System
Tam Kalite Güvencesi

Certificate Number: 2195-MED-1230801
Sertifika Numarası

Manufacturer:
Üretici

Sümer Uluslararası Sanayi ve Ticaret A.Ş.
Başkent Organize Sanayi Bölgesi Başkent Bulvarı No:81 Malıköy
Sincan/Ankara TÜRKİYE

Product(s):
Ürün(ler)

Products are stated on the following page(s).
Ürünler ilerleyen sayfa(lar)da belirtilmiştir.

Model(s):
Model(ler)

Product specifications are stated on the following page(s).
Ürün detayları ilerleyen sayfa(lar)da belirtilmiştir.

Reference Report No:
Referans Rapor No

MM0549-P007-R01, MM0549-P007-R02, MM0549-P007-R03, MM0549-P008-R01,
MM0549-P008-R04, MM0549-P008-R05

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyonundaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla sınırlıdır. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla sınırlıdır.

This EC certificate is valid till 2024-05-26.

Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: 2012-11-03
Revision No./ Revizyon No.: 09 Rev./Rev.
Revision Date/ Revizyon Tarihi: 2021-05-17



Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST

Certificate Number: 2195-MED-1230801
Sertifika Numarası

Product Specifications:
Ürün Detayları

1. Autoclaves / Otoklavlar						
Product Name Ürün Adı	Models Modeller					
Prismatic Autoclave Prizmatik Otoklav	Flywheel Door Prismatic Autoclave Series Volan Kapı Prizmatik Otoklav Serisi	SM-1VK	ELENA-1VK	OT-1VK	ADELA-1VK	100 L, 125 L, 150 L, 175 L, 200 L, 225 L, 250 L, 300 L, 325 L, 400 L, 425 L, 450 L, 470 L, 490 L, 500 L, 538 L, 580 L, 600 L, 628 L, 670 L, 700 L, 718 L, 760 L, 800 L, 900 L, 1000 L, 1200 L
	Double Flywheel Door Prismatic Autoclave Series Çift Volan Kapı Prizmatik Otoklav Serisi	SM-1CVK	ELENA-1CVK	OT-1CVK	ADELA-1CVK	
	Sliding Door Prismatic Autoclave Series Kayar Kapı Prizmatik Otoklav Serisi	SM-2KK	ELENA-2KK	OT-2KK	ADELA-2KK	
	Double Sliding Door Prismatic Autoclave Series Çift Kayar Kapı Prizmatik Otoklav Serisi	SM-2CKK	ELENA-2CKK	OT-2CKK	ADELA-2CKK	
Laboratory Type Vertical and Horizontal Autoclave Laboratuvar Tip Dik ve Yatay Otoklav	Laboratory Type Vertical Autoclave Laboratuvar Tip Dik Otoklav	SM-3D	OT-3V	ADELA-3D	ELENA-3V	60 L, 75 L, 90 L, 115 L
	Laboratory Type Horizontal Autoclave Laboratuvar Tip Yatay Otoklav	SM-3Y	OT-3Y	ADELA-3Y	ELENA-3Y	
Autoclave with Washing Function Yıkama Fonksiyonlu Otoklav	Flywheel Door Autoclave with Washing Function Series Volan Kapılı Yıkamalı Otoklav Serisi	SM-4VK	OT-4VK	ADELA-4VK	ELENA-4VK	96 L, 125 L, 175 L, 250 L
	Sliding Door Autoclave with Washing Function Series Kayar Kapılı Yıkamalı Otoklav Serisi	SM-4KK	OT-4KK	ADELA-4KK	ELENA-4KK	

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Product Specifications:

Ürün Detayları:

2. Tabletop Autoclave / Masaüstü Otoklav					
Product Name Ürün Adı	Models Modeller				
Tabletop Autoclave Masaüstü Otoklav	Single Door Tabletop Autoclave Tek Kapılı Masaüstü Otoklav	OT 18	OT 23	18 L, 23 L, 32 L, 40 L	
		OT 32	OT 40		
		ADELA 18	ADELA 23		
		ADELA 32	ADELA 40		

3. Washer and Disinfector Device / Yıkama ve Dezenfeksiyon Cihazı						
Product Name Ürün Adı	Models Modeller					
Washer and Disinfector Device Yıkama ve Dezenfeksiyon Cihazı	Single Door Washer and Disinfector Device Tek Kapılı Yıkama ve Dezenfeksiyon Cihazı	SM YKD-1	ELENA-1	WD-1	ADELA-1	200 L, 225 L, 230 L, 250 L, 360 L, 500 L
	Under Bench Washer and Disinfector Device Tezgahaltı Yıkama ve Dezenfeksiyon Cihazı	SM YKD-1	ELENA-1	WD-1	ADELA-1	100 L, 135 L, 150 L, 175 L
	Dental Washer and Disinfector Device Dental Yıkama ve Dezenfeksiyon Cihazı	SM YKD-1	ELENA-1	WD-1	ADELA-1	40 L, 60 L
	Double Door Washer and Disinfector Device Çift Kapılı Yıkama ve Dezenfeksiyon Cihazı	SM YKD-2	ELENA-2	WD-2	ADELA-2	200 L, 225 L, 230 L, 250 L, 360 L, 500 L

4. Blood Bank Refrigerator / Kan Saklama Dolabı					
Product Name Ürün Adı	Models Modeller				
Blood Bank Refrigerator Kan Saklama Dolabı	BB-BSR	SM-KSD	ADELA	ELENA	150 L, 250 L, 350 L, 450 L, 550 L, 650 L, 750 L, 850 L, 950 L, 1050 L, 1250 L

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Product Specifications:

Ürün Detayları:

5. Breast Pump / Anne Sütü Sağma Pompası		
Product Name <i>Ürün Adı</i>	Models <i>Modeller</i>	
Breast Pump <i>Anne Sütü Sağma Pompası</i>	ADELA	BP1, BP2, BP3, BP4, BP5

6. Oxygen Production and Storage System / Oksijen Üretim ve Depolama Sistemi		
Product Name <i>Ürün Adı</i>	Models <i>Modeller</i>	
Oxygen Production and Storage System <i>Oksijen Üretim ve Depolama Sistemi</i>	OXYFRESH	30 L, 50 L, 70 L, 100 L, 150 L, 200 L, 250 L, 300 L, 400 L, 500 L, 600 L, 750 L, 1000 L, 1250 L, 1500 L, 1800 L, 2400 L

CERTIFICATE



Medical Devices Quality Management System

CERTIFICATE NO: 31304402

SÜMER ULUSLAR ARASI SAN. VE TİC. A.Ş.

Başkent Organize Sanayi Bölgesi Başkent Bulvarı No:81 Malıköy, Sincan / Ankara TÜRKİYE

EN ISO 13485:2016

Design, Production, Sales and Service of Central Sterilization Units and Steam Sterilizers (Autoclaves) , Washing Steam Sterilizer, Tabletop Autoclave, Vertical Autoclave, Washer and Disinfector Devices, Operating Tables and Orthopedic Traction Set, Blood-Vaccine-Serum-Kit Storage Cabinets and Heating Cabinets, Oxygen Production and Storage System and Breast Pumps

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	13.02.2013
Issue Date	27.12.2021
Expiry Date	26.12.2024
Revision Date/No	27.12.2021 / 6



TÜRKAK BDS NO
YS-905C-C6D1



Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on <http://public.szutest.com.tr> or by using BDS No on <https://tdbs.turkak.org.tr>.



CERTIFICATE

to

SÜMER ULUSLARARASI SAN. VE TİC. A.Ş..

MERKEZ:

GMK Bulvarı 7/11
06440 , Kızılay - ANKARA /
TURKEY

FABRİKA:

IVOKSAN Matbaacılar Sitesi
1514 Sok. No 38-40,
06378 Yenimahalle - ANKARA /
TURKEY

manufacturing

the series of washer disinfectors:

Cleaning and Disinfection Devices

SM-YKD 1 100,135,150,175,200,225,250 (Single Door) &

SM-YKD 2 100,135,150,175,200,225,250(Double Door),

WD 1 100,135,150,175,200,225,250 (Single Door) &

WD 2 100,135,150,175,200,225,250 (Double Door)

It is hereby certified that the above named machine

fulfill the requirements and therefore the type test of EN ISO 15883-1 (2009)

„General requirements, definitions and tests“

and EN ISO 15883-2 (2009)

„Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.“

Identification Number: 1318260/044



Bischofshofen, 2013-07-05

Prof. Dr. med. H.-P. Werner

Managing Director

Medical Specialist for Hygiene and Microbiology

 sümer®
adeLa-OT
series



STEAM STERILIZERS
DATASHEET

SZUTEST
CE2195

ISO13485
certified



ADELA-OT series steam sterilizers are designed and manufactured regarding the manufacturing and product standards.

Medical Device Directive	: MDD 93/42/EEC / 2007/47/EC
Medical Device Class	: Class IIb, MDD 93/42/EEC, 2007/47/EC (Annex IX)
Low Voltage Directive	: 2014/35/EU - EN 61010-2-040 – EN 61010-1 EN 60601-1
EMC Directive	: 2014/30/EU EN 60601-1-2 – EN 61326-1
Pressure Equipments Directive	: PED 2014/68/EU : EN 13445-1, -2, -3, -4, -5
Steam Sterilizer Directive	: EN285
Quality Mangement System	: ISO 9001
Medical Devices Quality Mangement System	: ISO 13485
Enviromental Management Systems	: ISO 14001

®“Type tests” of Sümer A.S. Steam sterilizers are performed and certified according to the directives of EN 285 and TS EN 17665-1-2 by The German accreditation company HYGCEN GmbH.



General Characteristics

Control System	PLC CPU Microprocessor
Operation Mod	Fully Automatic / Button Command
Screen Type	Multi-Color TFT, LCD Touch Screen
Screen Size	7,0" (10,0" optional)
Keypad	Touch Screen
Printer	40 Character /Line , Thermal Printer
Remote Control and Communication	RS 232 Port / USB , Ethernet (optional)
Warning Sytem	Visual & Audio & Printed
Data Storage	Up to 200 Cycles
Monitoring	Touch Screen, Anaolgue Gauges for Chamber, Jacket, Generator and Air Pressure (Manometer)
Mobility	4 Easy positioning on 4 swivel castors and firm fixing on legs
Steam Generator	with pneumatic valves

Standard Programs

Medical & Surgical Instruments (134°C)	~ 60 min
Textile Materials (134°C)	~ 60 min
Rubber Articles (121°C)	~ 80 min
Liquids in Glass Container (121°C)	~ 60 min
Liquids in Glass Container (125°C)	~ 60 min
Flash (134°C)	~ 20 min
Prion (134°C)	~ 90 min
Bowie & Dick Test (134°C)	~ 45 min
Vacuum Leak Test	~ 25 min
Customizable Program Capacity	99

Process times are load-dependent and approximate. They refer to full process including drying with an average load.

Safety and Quality

√ Protects operator from electrical current leaks
√ Short circuit protection.
√ Safety valve
√ Hepa filter for air filtration.
√ Water level control via buoy in generator.
√ Pneumatic Valves for precise exhausting.
√ Leak test.
√ Password protection.
√ Sensors against obstructions on the doors pathway
√ Doors locks under pressure.
√ Emergency stop button.
√ Unable to open both doors at once double door models.

Horizontal loading

The loading and unloading of the boxes are carried out through 2 separate doors, intended for the receiving area of the non-sterile boxes and sterile area 2 doors

Internal construction, sterilization chamber, generator in stainless steel AISI 316L

Exterior construction, casing, sides in stainless steel AISI 304

Sterilization chamber: rectangular

Vertical automatic pneumatic door opening system

The sealing of the doors must be ensured by silicone gaskets with the help of the pneumatic and vacuum system

The door must be designed with a safety system to prevent injury to the user

Sterilization procedure: with internal steam generator

Water level monitoring system in the generator

Internal heaters with separate control and short circuit safety

Equipped with water-based vacuum pump, integrated

Equipped with steam generator filling water pump, integrated

Evaporator for drainage system

Internal stainless steel, pneumatic valves

Pressure equalization in the sterilization chamber ensured by HEPA filter

Overheat safety

Safety door opening system in case of pressure in the sterilization chamber

Autoclave door locking system that prevents the cycle from starting if the door is open

The door remains locked until the end of the sterilization process,

Acoustic, visual alarms

Alarms: power failure, low temperature, sterilization cycle failure

Sterilization time adjustable

Preset sterilization regimes ≥ 5 programs

Sterilization regimes that can be programmed by the user ≥ 10 programs

The device must be equipped with software, electrical and mechanical safety protection in case of faults

Interface and menu language Romanian or Russian

Setting by the user of the desired sterilization regime

Tests supported: vacuum (leakage) test and Bowie-Dick test

Electronic control Microprocessor

Independent electronic pressure sensors "for the generator and the chamber sterilization"

The device must be equipped with an emergency stop button on the front panel

The outer surface should not heat up

Thermal printer

Process monitoring on the LCD touch screen

Real-time monitoring of the temperature in the sterilization room

chamber pressure (digital)

internal pressure (digital)

pressure generator (digital)

sterilization cycle graphics

Sterilization cycle Positive pressure cycle

Vacuum cycle

Selectable pre and post vacuum

Vacuum drying system

Time setting facilities temperature automatic release of vapors printing the results

Support with shelves compatible for the placement of instruments and cases ≥ 2 supports datable shelves min. 2 pcs. to each support

Accuracy of sterilization time ± 1 min

Temperature range: 121 -134 degrees C

Temperature accuracy $\pm 2^{\circ}\text{C}$

TECHNICAL DATA SHEET

CHAMBER VOLUME (LITER) AND DIMENSIONS													
MODELS	SINGLE DOOR						DOUBLE DOOR						
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Height (mm)	390	390	500	500	670	670	390	500	500	670	670	670	670
Width (mm)	390	390	500	500	670	670	390	500	500	670	670	670	670
Depth (mm)	700	1000	1000	1300	1000	1300	1000	1000	1300	1000	1300	1600	2000
STU Capacity	1	1,5	1,5	2	6	8	1,5	1,5	2	6	8	10	12

DEVICE DIMENSION													
MODELS	SINGLE DOOR						DOUBLE DOOR						
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Height (mm)	1655	1655	1765	1765	1935	1935	1655	1765	1765	1935	1935	1935	1935
Width (mm)	885	885	995	995	1165	1165	885	995	995	1165	1165	1165	1165
Depth (mm)	1125	1325	1325	1625	1325	1625	1325	1325	1625	1325	1625	1925	2325

PACKING DIMENSION													
MODELS	SINGLE DOOR						DOUBLE DOOR						
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Height (mm)	1920	1920	2030	2030	2200	2200	1920	2030	2200	2200	2200	2200	2200
Width (mm)	1070	1070	1180	1180	1350	1350	1070	1180	1180	1350	1350	1350	1350
Depth (mm)	1280	1580	1580	1880	1580	1880	1580	1580	1880	1580	1880	2175	2575

DEVICE WEIGHT													
MODELS	SINGLE DOOR							DOUBLE DOOR					
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Weight (Kg)	500	600	670	770	850	1000	700	800	900	1050	1200	1450	1680

GENERATOR DIMENSION													
MODELS	SINGLE DOOR						DOUBLE DOOR						
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Generator Power (3 Phase/400± 10VAC)	20	20	30	30	40	40	20	30	30	40	40	60	60
Installation Power (kW)	25	25	35	35	45	45	25	35	35	45	45	65	65
Generator Volume(L)	25	25	50	50	75	75	25	50	50	75	75	100	100

TRANSPORT TROLLEY DIMENSION													
MODELS	SINGLE DOOR						DOUBLE DOOR						
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Width (mm)	480	480	590	590	660	660	480	590	590	660	660	660	660
Height (mm)	1000	1000	1100	1100	1100	1100	1000	1100	1100	1100	1100	1100	1100
Depth (mm)	880	1180	1180	1480	1180	1480	1180	1180	1480	1180	1480	1780	1780

LOADING CART DIMENSION													
MODELS	SINGLE DOOR						DOUBLE DOOR						
	100 L	150 L	250 L	325 L	425 L	580 L	150 L	250 L	325 L	425 L	580 L	718 L	900 L
Width (mm)	380	380	490	490	660	660	380	490	490	660	660	660	660
Height (mm)	365	365	430	430	530	530	365	430	430	530	530	530	530
Depth (mm)	660	960	960	1260	960	1260	960	960	1260	960	1260	1560	960

Temperature

Range	115°C - 137°C (Chamber)
Measurement	PT 100 (DIN A Class)
Sensor Position	Chamber (1)

Pressure

Measurement	Pressure Sensores (4)
Sensor Position	Chamber (1), Jacket(1), Generator (1), Gasket(1)

Vacuum

Source	Pump, Water Ring (2.2kW)
Pre-Vacuum	Yes

Device Construction

Body	AISI 304 Stainless Steel
Chamber	6mm, AISI 316L Stainless Steel
Jacket	3mm, AISI 316L Stainless Steel
Door	10mm, AISI 304 Stainless Steel
Panel Cover	1-1,5 mm AISI 304 Stainless Steel
Pipes	AISI 304 Stainless Steel
Chamber Polishing	Sandblasting, Electropolishing (Standard)

Drainage

Water	Inclined pipe to be installed onsite with at least 2 m of length (Diameter: 2" -3")
Steam	Pneumatic valve, software controlled
Air	Vacuum Motor (Built-in)

INSTALLATION CONDITIONS: At least 60 cm. space is needed on both lateral sides of the device to provide an effective technical service. Exhaust fan or ventilation funnel needs to be placed above the device for an effective evacuation of heat.

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Specifications are given for reference only and are subject to
change without any previous notice.
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Jacket

Test Pressure	3,75 Bar
Test Temperature	140 °C
Working Temperature	134 °C
Working Pressure	2,5 Bar

Generator

Test Pressure	5,25 Bar
Test Temperature	150 °C
Working Temperature	144 °C
Working Pressure	3,5 Bar
Water Level Protection	*CRES / AISI 304 SS

* CRES: Anti Corrosive Stainless Steel



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