

**sümer®**

MDD 93/42/EEC-2007/47/EC

Declaration of Conformity

Company Name : Sümer Uluslararası Sanayi ve Ticaret A.Ş.
Company Address : Başkent Organize Sanayi Bölgesi,
Başkent Bulvarı No:81 Malıköy, Sincan Ankara-TÜRKİYE
Tel / Fax : +90.312.503 0821 / +90.312. 394 6195
Web / E-Mail : www.sumerinc.com / sumer@sumeras.com
Product : Steam Sterilizer Devices
Classification : Medical Devices Directive Annex IX, according to15; IIb
EC Certificate No : 2195-MED-1230801
Validity : 26.05.2024

We undertake that "Steam Sterilizer Device" specified in the attached list conform the requirements of Medical Device Directives MDD 93/42/EEC / 2007/47/EC Annex.II Article 3., as valid from 16/04/2020. This Declaration of Conformity is valid up to 26.05.2024.



**Notified Body
Registry No
Name**

2195

: SZUTEST TEKNİK KONTROL VE BELGELENDİRME HİZMETLERİ
TİC. LTD. ŞTİ.

Address :

: SZUTEST Plaza Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774
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Osman ÇETİNEL
General Manager
16/04/2020, Rev9

**C € 2195**

Attached List

Attached List

Declaration Date	16/04/2020	Revision	9		
DIRECTIVE CE CLASSIFICATION STEAM STERILIZER					
EC Directive	MDD 93/42/EEC - 2007/47/EC - Annex.II Article.3 – Annex.IX, Rule 15, Class IIb				
Brand	Model Type	Volume	GMDN Code	UNSPSC Code	Medical Device Class
SÜMER	SM-1VK – OT-1VK – ADELA-1VK – ELENA-1VK Flywheel Door Prismatic Autoclave	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	38671	42281508	IIb
	SM-1CVK – OT-1CVK – ADELA-1CVK – ELENA-1CVK Double Flywheel Door Prismatic Autoclave				
	SM-2KK – OT-2KK – ADELA-2KK – ELENA-2KK Sliding Door Prismatic Autoclave				
	SM-2CKK – OT-2CKK – ADELA-2CKK – ELENA-2CKK Double Sliding Door Prismatic Autoclave				
	SM-3D – OT-3D – ADELA-3D – ELENA-3D Laboratory Type Vertical Autoclave	60 L,75 L,90 L,115 L			
	SM-3Y – OT-3Y – ADELA-3Y – ELENA-3Y Laboratory Type Horizontal Autoclave				
	SM-4VK – OT-4VK – ADELA-4VK – ELENA-4VK Flywheel Door Autoclave with Washing Function	96 L, 125 L, 175 L, 250 L			
	SM-4KK – OT-4KK – ADELA-4KK – ELENA-4KK Sliding Door Autoclave with Washing Function				
APPLIED STANDARDS		EN 60601-1, EN 61010-2-40, EN 61010-1, EN 60601-1-2, EN 61326-1, EN 62304, EN 285, EN 13445-1, EN 62366-1, EN 14971, EN 17665-1, EN 15223-1			