



sümer[®]

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

Declaration of Comformity

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 : Oxygen Production and Storage System
EC Certificate No : 2195-MED-1230801
Validity : 26.05.2024

We undertake that "Oxygen Production and Storage System" 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 07/04/2020.

This Declaration of Comformity is valid up to 26.05.2024.



Notified Body

Registry No : 2195
Name : SZUTEST TEKNİK KONTROL VE BELGELENDİRME HİZMETLERİ
TİC. LTD. ŞTİ.
Address : : SZUTEST Plaza Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774
Ümraniye/İstanbul
Tel : +90.216.469 46 66
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SÜMER
ULUSLARARASI SANAYİ VE TİCARET ANONİM ŞİRKETİ
Başkent OSB Başkent Bulvarı No: 81
Malıköy Sincan ANKARA
Tel: 0312 394 61 95 / Faks: 0312 394 61 95
Sincan M.D. 786 001 595

Şeyma Sena AKYOL
Quality Management Director
20.05.2021, Rev.1

C € 2195

Attached List

Declaration Date	20/05/2021	Revision	1	
DIRECTIVE CE CLASIFICACION 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	Medical Device Class
SÜMER	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	36271	Iib
APPLIED STANDARDS	EN 13485, EN 1041, EN 60601-1, EN 7396-1, EN 62366, EN 60601-1-6, EN 60601-1-2, EN 15223-1, EN 14971, EN 62304			