

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 : Medical Oxygen Production and Storage System
Classification : MDD 93/42/EEC – 2007/47/EC – Annex.II Article.3 – Annex.IX, Rule 15,
Class IIb
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 ISO 21969 High-pressure flexible connections for use with medical gas systems as valid from 07/04/2020. This Declaration of Conformity is valid up to 26.05.2024.



Notified Body
Registry No : 2195
Name : SZUTEST TEKNİK KONTROL VE BELGELENDİRME HİZMETLERİ
TİC. LTD. ŞTİ.
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Şeyma Sena AKYOL
Quality Management Representative
20/05/2021, Rev.01

CE 2195



ISO 21969

High-pressure flexible connections for use with medical gas systems

Declaration of Conformity

Attached List

DIRECTIVE CE CLASSIFICATION OXYGEN PRODUCTION AND STORAGE SYSTEM				
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
Declaration Date		20/05/2021	Revision	1

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