

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
EC Certificate No : 2195-MED-1230801
Validity : 26.05.2024

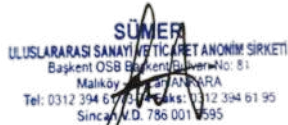
We undertake that "Medical Oxygen Production and Storage System" specified in the attached list conform the requirements of ISO 8573-1:2010 Class 1.4.1 Compressed air — Part 1: Contaminants and purity classes, as valid from 07/04/2020.

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.
Address : : SZUTEST Plaza Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774
Ümraniye/İstanbul
Tel : +90.216.469 46 66
Fax : +90.216.469 46 67


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			

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 8573-1 Compressed air-Part 1:Contaminants and purity classes 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.
Address : : SZUTEST Plaza Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774
Ümraniye/İstanbul
Tel : +90.216.469 46 66
Fax : +90.216.469 46 67

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 V.D. 745 001 8595

Şeyma Sena AKYOL
Quality Management Representative
20/05/2021, Rev.01

CE 2195



ISO 8573-1

Compressed air-Part 1:Contaminants and purity classes
Declaration of Conformity

Attached List

Declaration Date	20/05/2021	Revision	1	
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

CE 2195

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 8573-2 Compressed air - Contaminant measurement - Part 2: Oil aerosol content 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.
Address : : SZUTEST Plaza Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774
Ümraniye/İstanbul
Tel : +90.216.469 46 66
Fax : +90.216.469 46 67

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. 785 004 8595

Şeyma Sena AKYOL
Quality Management Representative
20/05/2021, Rev.01

CE 2195

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

CE 2195



sumer

ISO 8573-4

Compressed air - Contaminant measurement - Part 4: Particle content
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 : 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 8573-4 Compressed air - Contaminant measurement - Part 4: Particle content 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.
Address : : SZUTEST Plaza Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774
Ümraniye/İstanbul
Tel : +90.216.469 46 66
Fax : +90.216.469 46 67

SÜMER
ULUSLARARASI SANAYİ VE TİCARET ANONİM ŞİRKETİ
Başkent OSB Başkent Bulvarı No: 81
Malıköy - Sincan - ANKARA
Tel: 0312 394 61 22 / 0312 394 61 95
Sincan Y.D. Mes 001 1895

Şeyma Sena AKYOL
Quality Management Representative
20/05/2021, Rev.01

CE 2195



Sümer

ISO 8573-4

Compressed air - Contaminant measurement - Part 4: Particle content
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

CE 2195