



PRODUCT CERTIFICATION
BODY
CEPROM-CERT



CEPROM[®] S.A.

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CERTIFICATE OF CONFORMITY

No. 3267-CT-32024

Technical File no. 3267-CT-32024

Applicant:

S.C. OXYHELP INDUSTRY S.R.L.

050652 Bucharest, District 5, no. 15,
Panduri Road, bldg. P18, entr. 1, 2nd floor, apt. 7
Romania.

Manufacturer:

S.C. OXYHELP INDUSTRY S.R.L.

050652 Bucharest, District 5, no. 15,
Panduri Road, bldg. P18, entr. 1, 2nd floor, apt. 7
Romania.

Description of product:

Product:

HYPERBARIC CHAMBER

Models:

OxyLife I 80, I 90, C2, C3, C4

Reference standards:

**EN ISO 12100:2010, EN 60204-1:2018,
EN IEC 55014-1:2021, EN IEC 55014-1:2021,
EN IEC 61000-3-2:2019+A1:2021, EN 61000-3-3:2013+A1:2019,
EN 61000-4-2:2009, EN 61000-4-4:2012, EN 61000-4-5:2014+A1:2017**

Based on our assessment we confirm that the product is in accordance with the technical requirements of the above standards and hence fulfils the technical requirements of the

Machinery Directive 2006/42/EC

Low Voltage Directive 2014/35/EU

Electromagnetic Compatibility Directive 2014/30/EU

The manufacturer shall affix the CE marking to each product that is in conformity with those described in this Certificate of conformity, after completion of the EU Declaration of Conformity and in accordance with the above directives.

The assessment activity for the product described in this Certificate of Conformity was carried out in compliance with Scheme 1a, cf. EN ISO/IEC 17067:2013 with Assessment Report and doesn't belong in the scope of the notification under harmonized European Union product legislation.

The manufacturer must ensure the assessment of conformity with internal controls on the manufacture of the above product, in accordance with Annex VIII of 2006/42/EC Directive and Annex III of 2014/35/EU Directive and Annex II of 2014/30/EU Directive.

This Certificate of Conformity was issued on voluntary basis of manufacturer and is only valid for the product and configuration described (annex), in conjunction with the detailed test data and with all applicable legal requirement for the product.

Annex: Product identification – 2 pages

Issuing Date: 19.02.2024

Expiry Date: 18.02.2029



EUROPEAN UNION

Satu Mare, Romania

GENERAL MANAGER

eng. Cristian SOPONOS

CEPROM-CERT Manager

eng. Vasile ZELE



E.S.

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ANNEX
to the Certificate of Conformity no. 3267-CT-32024

PRODUCT IDENTIFICATION

The Product: **HYPERBARIC CHAMBER**
*models: **OxyLife I 80, I 90, C2, C3, C4**
*assessed type: **OxyLife C2, serial no. C2/003/2024**
*manufactured by: **S.C. OXYHELP INDUSTRY S.R.L.**
*headquarters address: *050652 Bucharest, District 5, no. 15, Panduri Road, bldg. P18, entr. 1, 2nd floor, apt. 7, Romania.*
*place of manufacture: *100544 Ploiești, no. 108D, Lupeni street, Hall C3, Prahova County, Romania.*
*domain of use: *The product is used to human hyperbaric oxygen therapy.*

Technical File content:

- General description of the machinery;
- General drawing;
- Electrical diagram for driving and control;
- Full detailed drawings required to check the conformity;
- The description of applied protective measures;
- The list of used standards and Essential health and safety requirements covered by them;
- Assessment Report no. 3267-CT-32024/16.02.2024, issued by CEPROM-CERT;
- LVD Test Report no. 1191/05.02.2024, issued by CEPROM-CERT
- EMC Test Report no. 1192/05.02.2024, issued by CEPROM-CERT;
- EC declaration of conformity of the components incorporated into the machinery;
- Instruction Manual.
- EC Declaration of conformity

CEPROM-CERT Manager
eng. Vasile ZELE





PRODUCT IDENTIFICATION

The Product: **HYPERBARIC CHAMBER**

*constructive and functional characteristics:

Characteristics	M.U.	OxyLife I 80	OxyLife I 90
No. of places in the hyperbaric chamber	-	1	1
Person weight	lbs	300	300
Internal volume	l	1150	1450
Maximum operating pressure	kPa	49	
Protection level	-	IP 44	
Weight	lbs	352.7	418.8
Dimensions	mm	Ø 800 (±5) L=2300 (±5) H=950	Ø 900 (±5) L=2300 (±5) H=1050
Material	-	Aluminum alloy	
Standard color	-	white	
Power supply	-	230V/50-60Hz 110-120V/60Hz	

Characteristics	M.U.	OxyLife C2	OxyLife C3	OxyLife C4
No. of places in the hyperbaric chamber	-	2	4	5
Person weight	lbs	300	300	300
Internal volume	l	approx. 4464.1	approx. 6415.3	approx. 8366.5
Maximum operating pressure	kPa	49		
Protection level	-	IP 44		
Weight	lbs	1477	2028.2	2755.7
Dimensions	mm	Ø 1950 (±5) L=2135 (±5) H=2250	Ø 1950 (±5) L=2900 (±5) H=2250	Ø 1950 (±5) L=3652 (±5) H=2250
Material	-	Aluminum alloy		
Standard color	-	white		
Power supply	-	230V/50-60Hz		

Manager CEPROM-CERT
ing. Vasile ZELE

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