



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 511074

Issued To:

Perry Baromedical Corporation

3750 Prospect Avenue

Riviera Beach

Florida 33404 USA

In respect of:

The design and manufacture of Hyperbaric Oxygen Treatment Chambers

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

Gary C Stade

First Issued: 2007-08-31

Date: 2021-05-18

Expiry Date: **2022-08-30**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.





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Supplementary Information to CE 511074

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Device code	Device name	Intended purpose per IFU
Class IIb		
MD 1102	Chambers co	Indicated for use for the following clinical medical conditions in accordance with the guidelines established by the Undersea and Hyperbaric Medical Society1(UHMS), as follows:
		Air or Gas Embolism
		Carbon Monoxide / Smoke Inhalation
		Compromised Skin Grafts and Flaps
		Crush injuries / Acute Traumatic Ischemias
		Decompression Sickness
		Enhanced Healing and Selected Problem Wounds
		Exceptional Blood Loss (Anemia)
		Gas Gangrene (Clostridial Myonecrosis)
		Intracranial Abscess
		Necrotizing Soft Tissue Infections
		Radiation Tissue Damage (Osteoradionecrosis)
		Refractory Osteomyelitis
		Thermal Burns
		Idiopathic sudden sensorineural hearing loss

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.





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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:

CE 511074

Date:

2021-05-18

Issued To:

Perry Baromedical Corporation

3750 Prospect Avenue

Riviera Beach Florida

33404 USA

Subcontractor:

Service(s) supplied

EUCEREP B.V. Roald Dahllaan 33 5629MC – Eindhoven The Netherlands **EU Representative**

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