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By Royal Charter

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

First Issued: **2007-08-31** Date: **2021-05-18** Expiry Date: **2022-08-30**

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Supplementary Information to CE 511074

Issued To:

Perry Baromedical Corporation
3750 Prospect Avenue
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33404
USA

Device code	Device name	Intended purpose per IFU
Class IIb		
MD 1102	Monoplace Hyperbaric Chambers	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

First Issued: **2007-08-31** Date: **2021-05-18** Expiry Date: **2022-08-30**

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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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