PERRY BAROMEDICAL
Hyperbaric Therapy Systems

3750 PROSPECT AVENUE
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FLORIDA, USA
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MANUFACTURER SELF-DECLARATION

Date: 14th June-2023

REF:
BSI Group The Netherlands B.V. NB#2797 Reference Certificate: CE 511074
EC Certificate – Full Quality Assurance System – Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4
Expiry date: 30 August 2022
EU2023-607/630742 Notified Body Confirmation Letter issued by BSI: 18 May 2023

Perry Baromedical Corporation declares fulfillment of the conditions specified in the MDR Article 120.3 as amended by (EU) 2023/607 for the following devices:

Legacy devices covered by this declaration:
Monoplace Hyperbaric Chambers (Sigma 34, 36 and 40)
Device Classification: Class IIb (Rule 11)

Applicable end date of the certificate validity and MDR transition period: 31st December 2028
The above referenced certificate CE 511074, remains valid at the end of the period indicated on the certificate (August 30, 2022), and as of the date of this declaration, for the above listed legacy medical devices.

BSI Group The Netherlands B.V. (Notified Body ID#2797) has issued a confirmation letter on February 7th 2023, confirming that the certificate referred to above covering the legacy devices specified above has expired by the course of time and was valid at the date of its expiry, it neither having been suspended nor withdrawn.

Perry Baromedical Corporation submitted a formal application and completed and signed a written agreement with BSI Group The Netherlands B.V. (MDR Notified Body ID #2797) for MDR certification of the devices specified above in June, 2022, prior to the expiry of the certificate referred to above.

Perry Baromedical Corporation confirms that as of the date of this declaration, we fulfill the following conditions, as specified for the application of the extension of the validity of the certificate referred to per the MDR Article 120.3 as amended by (EU) 2023/607 for the devices specified above:

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1. The devices specified continue to comply with the requirements of the Medical Device Directive (93/42/EEC) (the "MDD"). The NB #2797 has continuously maintained the appropriate surveillance activities requirements for the above specified devices during the interim period, and all outcomes of NB directive appropriate surveillance have been positive or no NB actions on the certificate referred to above have been issued.
2. There have been no significant changes to the design and intended purpose of the legacy devices specified above per the definition in MDCG 2020-3. Perry Baromedical Corporation has and continues to maintain appropriate change control processes, and monitoring of change control history which is audited by NB #2797.
3. The devices specified above continue to remain safe. There have been no adverse events reported concerning the devices specified above and Perry Baromedical Corporations Post-Market Surveillance has identified no reported user safety concerns regarding these devices. There have also been no NB actions on the certificate referred to above resulting in suspension or scope restrictions due to NB QMS audits or vigilance report reviews.
4. Perry Baromedical Corporations Quality Management System (QMS) complies with the MDR Article 10(9) at the date of this declaration. The NB performed an audit of our QMS documentation at the time of application for conformity assessment to MDR, and it has been found to comply with the requirements of Annex IX Section 2.1 and Article 10(9) of MDR.
5. Perry Baromedical Corporation submitted a formal application and completed and signed a written agreement with BSI Group The Netherlands B.V. (MDR Notified Body ID #2797) for MDR certification of the devices specified above in June, 2022. QMS and technical documentation for the conformity assessment of the devices have already been submitted.

Silvia Valik June 14th, 2023

Silvia Valik
Director of Regulatory Affairs
Perry Baromedical Corp

PERRY BAROMEDICAL
Hyperbaric Therapy Systems
HYPERBARIC THERAPY SYSTEMS
MONOPLACE • DUALPLACE • MULTIPLACE

Appendices:

1. BSI Group The Netherlands B.V. NB#2797 Reference Certificate: CE 511074
   EC Certificate – Full Quality Assurance System – Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

Perry Baromedical Corporation
3750 Prospect Avenue
Riviera Beach
Florida
33404
USA

19 May 2023

Notified Body Confirmation Letter
Reference: EU2023-607/630742

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Perry Baromedical Corporation
3750 Prospect Avenue
Riviera Beach
Florida
33404
USA

SRN Number: US-MF-000020630

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the

corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Alun Hopkins

Digitally signed by Alun Hopkins
Date: 2023.05.19 18:21:35 +01'00'

Alun Hopkins

BSI Scheme Manager

bsi.

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SIGMA 34 Monoplace Hyperabric Chamber	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 511074
SIGMA 36 Monoplace Hyperabric Chamber	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 511074
SIGMA 40 Monoplace Hyperabric Chamber	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 511074

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/05/19	Initial issue

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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

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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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 511074

Issued To:

Perry Baromedical Corporation
3750 Prospect Avenue
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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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EC Certificate - Full Quality Assurance System

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

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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