



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

8/11/2007  
Submission ID: DW-2007-0609

Hyperbaric Health Pty Ltd  
119-123 Woodlands Drive  
BRAESIDE VIC 3195

Attention: Glen Hawkins

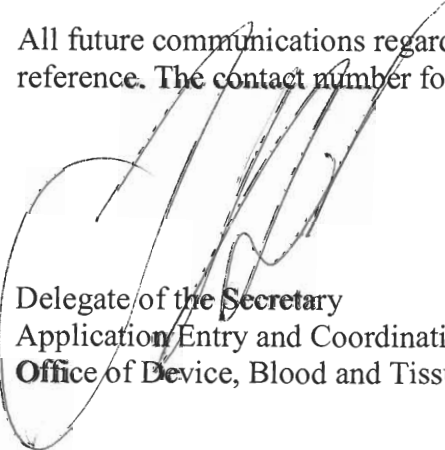
**NOTIFICATION OF INCLUSION OF A MEDICAL DEVICE**  
**Application for inclusion in the ARTG: DV-20071022-DA-048904-11**  
**Your Reference: Perry Baromedical Sigma 34/40**  
**ARTG No: 147088**

Attached please find the certificate(s) provided as a result of your recent application(s) for inclusion of a Medical Device on the Australian Register of Therapeutic Goods (ARTG).

**These goods are included subject to the conditions as stated in the Certificate(s) for Inclusion of a Medical Device related to this notification.**

The TGA Financial Services Group will issue an invoice for annual fees. The inclusion of the goods will commence on the day specified for the **purpose in the Certificate** for Inclusion of a Medical Device. The goods **may not be supplied prior to this date. Continued inclusion will** be subject to payment of the annual fees.

All future communications regarding the approval should include the ARTG Number as a reference. **The contact number** for any questions is 1800 141 144.



Delegate of the **Secretary**  
Application Entry and Coordination Section  
**Office of Device, Blood and Tissues**

**ENC:** Certificate for Inclusion of a Medical Device

## **CERTIFICATE FOR INCLUSION OF A MEDICAL DEVICE**

**ARTG Number** 147088

**ARTG Labelname** Hyperbaric Health Pty Ltd - Chamber, patient, hyperbaric

**Sponsor** Hyperbaric Health Pty Ltd

**Commencement Date** 07/11/2007

**Manufacturer** Perry Baromedical Corporation United States Of America

**Device Class** Class IIb  
**GMDN Code** 12061 Chamber, patient, hyperbaric

**ARTG Product Number and Name**  
235321 Chamber, patient, hyperbaric

**The above Medical Device is Included in the Australian Register of Therapeutic Goods subject to the following conditions**

***Standard Conditons***

*The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.*

*The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.*

*For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.*

*Each sponsor shall retain records of the distribution of all of the sponsor's medical*

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*devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.*

*The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.*

*The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.*

*Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.*

*A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.*

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