

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 680871**
Issued To: **Paxman Coolers Ltd.,
International House,
Penistone Road,
Fenay Bridge,
Huddersfield
HD8 0LE
United Kingdom**

In respect of:

Manufacture of Scalp Cooling Systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2018-01-30**

Date: **2020-12-22**

Expiry Date: **2023-01-29**

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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.

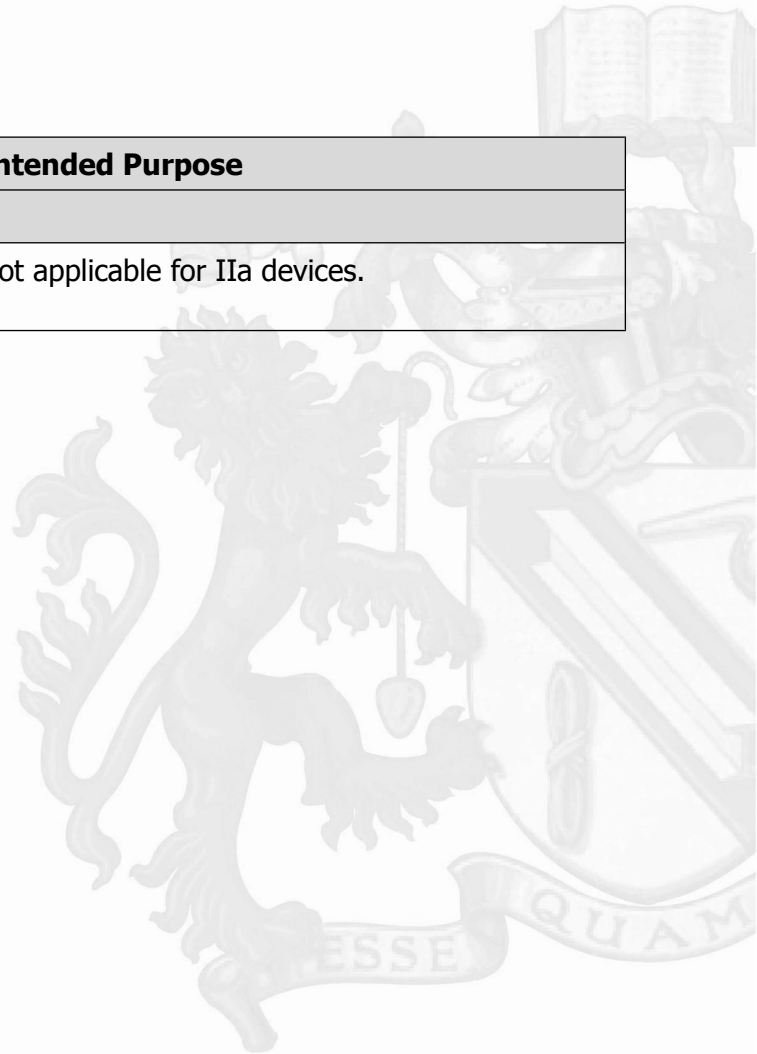
This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 680871

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NBOG Code(s)	Device Description	Intended Purpose
Class IIa		
MD 1403	Devices for Hypothermia/ Hyperthermia	Not applicable for IIa devices.



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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:

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Subcontractor:

Service(s) supplied

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

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Certificate History

Certificate No: **CE 680871**
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Date	Reference Number	Action
30 January 2018	8799295	First Issue.
11 March 2019	8799365	Traceable to NB 0086.
Current	3342327	Added subcontractor Emergo Europe B.V. as EU Representative. Addition of device table.

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