

# EC Certificate - Production Quality Assurance

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

**No.****CE 680871**

Issued To:

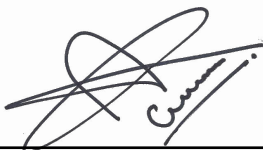
**Paxman Coolers Ltd.,  
International House,  
Penistone Road,  
Fenay Bridge,  
Huddersfield  
HD8 0LE  
United Kingdom**

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):



Albert Roossien, Regulatory Lead

First Issued: **2018-01-30**Date: **2019-03-11**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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## Certificate History

Certificate No: **CE 680871**  
 Date: **2019-03-11**  
 Issued To: **Paxman Coolers Ltd.,  
 International House,  
 Penistone Road,  
 Fenay Bridge,  
 Huddersfield  
 HD8 0LE  
 United Kingdom**

Date	Reference Number	Action
30 January 2018	8799295	First Issue.
Current	8799365	Traceable to NB 0086.

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