



**DECLARATION of CONFORMITY**

**CLASS IIA MEDICAL DEVICE  
AS DEFINED IN THE DIRECTIVE 93/42/EEC ANNEX IX RULE 9**

<b>MANUFACTURER</b>		
<b>Manufacturer's name</b>	<b>Manufacturers Address</b>	<b>Telephone/email</b>
<b>PAXMAN COOLERS LTD</b>	International House, Penistone Road Fenay Bridge, Huddersfield, HD8 0LE	Tel: +44 (0) 1484 349 444 <a href="mailto:info@paxmanscalpcooling.com">info@paxmanscalpcooling.com</a>

<b>EU AUTHORIZED REPRESENTATIVE</b>		
<b>Name of Company</b>	<b>Address</b>	<b>Telephone/email</b>
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

Name of Device Identification PAXMAN Scalp Cooling System (PSCS)  
Models: PSCS I, PSCS II

The above medical devices are RoHS compliant conforming with the directive 2011/65EU

It is hereby declared that the medical device specified above conforms with the provisions of the Directive 93/42/EEC of 14<sup>th</sup> June, 1993, amended 2007/47/EC

This Declaration is supported by:

- Technical documentation required by the MDD retained by:
- The company's Management Representative
- EC Quality systems, Annex V registration with BSI Certification services
- Notified Body No. 2797
- Approved certification No. 680871

Issued by: BSI Date: 15/12/2020

Signature: *A. Sheldrake*

Alexandra Sheldrake Position: Head of Quality

Valid from: 15th, December 2020

Issue 1