

DECLARATION of CONFORMITY

Class IIa Medical Device

As defined in the directive 93/42/EEC
annex IX rule 9

Manufacturer's name	Paxman Coolers
Manufacturer's address	International House, Penistone Road, Fenay Bridge Huddersfield, HD8 0LE
Name Of Device Identification	Paxman Scalp Cooling System (PSCS)

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 14th June, 1993, amended 2007/47/EC

This declaration is supported by:

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

Issued by : BSI

Date: 11/3/2019

Signed  Valid from : 11th , March 2019 Position: Head of Quality & Technical