By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 644325**

Issued To: **Pyrexar Medical Inc**
1825 West Research Way
Unit E
Salt Lake City
Utah
84119
USA

In respect of:

Design and Manufacture of RF Hyperthermia Cancer Treatment Systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **18 April 2016** Date: **18 April 2016** Expiry Date: **17 April 2021**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 644325**
Date:	**18 April 2016**
Issued To:	**Pyrexar Medical Inc** **1825 West Research Way** **Unit E** **Salt Lake City** **Utah** **84119** **USA**

Subcontractor:	**Service(s) supplied**
Dr. Sennewald Medizintechnik GmbH Schatzbogen 86 Münich 81829 Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 644325**

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Date	Reference Number	Action
18 April 2016	8429549	First Issue

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