

# 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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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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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:

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**Subcontractor:**

**Service(s) supplied**

Dr. Sennewald Medizintechnik GmbH  
Schatzbogen 86  
München  
81829  
Germany

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

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<b>Date</b>	<b>Reference Number</b>	<b>Action</b>
18 April 2016	8429549	First Issue

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