By Royal Charter

EC Certificate - Full Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

No. **CE 538785**

Issued To: **IsoRay Medical**
350 Hills St., Suite 106
Richland
Washington
99354
USA

In respect of:

The design, development and manufacture of sealed radionuclide sources and preloaded brachytherapy seeds.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 90/385/EEC, Annex 2, excluding Section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of devices covered by this certificate an EC design-examination certificate according to 90/385/EEC, Annex 2, section 4 is required.

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

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2008-12-23** Date: **2019-02-26** Expiry Date: **2023-12-22**

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Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

List of Significant Subcontractors

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

Certificate No:	**CE 538785**
Date:	**2019-02-26**
Issued To:	**IsoRay Medical** **350 Hills St., Suite 106** **Richland** **Washington** **99354** **USA**

Subcontractor:	**Service(s) supplied**
CoorsTek Bioceramics LLC 2451 Riverside Parkway Grand Junction Colorado 81505 USA	**Manufacture**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Ethicon Inc. Route 22 Somerville NJ 08876-0151 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Poly-Med, Inc. 51 Technology Drive Anderson SC 29625 USA	**Manufacture**
Riverpoint Medical, LLC 825 NE 25th Avenue Portland Oregon 97232 USA	**ETO Sterilization** **Manufacture** **Packaging**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 538785**

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Date	Reference Number	Action
23 December 2008	7225631	First Issue
23 March 2011	7544348	Addition of subcontractors Poly-Med and Ethicon. Addition of EU Representative Emergo.
23 December 2013	8035851	Certificate renewal, changes to the list of significant subcontractors 1) change of address of Poly-Med, Inc. from 6309 Highway 187, Anderson, SC 29625, USA to 52 Technology Drive, Anderson, SC 29625, USA; 2) change of street address for C5 Medical Werks, Inc. from 2451 River Road to 2451 Riverside Parkway; 3) addition of Riverpoint Medical, 825 NE 25th Avenue, Portland, OR 97232, USA for the activity of manufacture of needles.
27 July 2016	8525528	Change to list of critical subcontractors: The name of C5 Medical Werks, Inc. replaced with CoorsTek, LLC.
Current	9648655	Renewal