bsi.

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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 December 2008** Date: **27 July 2016** Expiry Date: **22 December 2018**

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