

# EC Certificate - Full Quality Assurance System

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

**No.** CE 686185  
**Issued To:** Xcision Medical Systems, LLC  
9176 Red Branch Road, Suite O  
Columbia  
Maryland  
21045  
USA

In respect of:

**The design and manufacture of stereotactic radiotherapy devices for treatment of breast cancer.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-04-09**

Date: **2019-04-09**

Expiry Date: **2024-04-08**

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Page 1 of 2

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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## Supplementary Information to CE 686185

Issued To:

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**USA**

NBOG code(s)	Device Description	Intended purpose
<b>Class IIb</b>		
MD 1401, MD 1111, MD 1109	Radiotherapy device including patient positioning system and application software	Stereotactic radiotherapy device for treatment of breast cancer

First Issued: **2019-04-09**

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Page 2 of 2

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

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

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**Maryland**  
**21045**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
International Isotopes, Inc. (INIS) 4137 Commerce Circle Idaho Falls 83401 USA	<b>Crucial Supplier</b>
Peter Hoban Consulting, Ltd. 2 Baytree Close Crockernwell EX6 6NS United Kingdom	<b>EU Representative</b>

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 686185**  
 Date: **2019-04-09**  
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**Columbia**  
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**USA**

Date	Reference Number	Action
Current	8871440	First Issue

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Page 1 of 1

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