

EC Certificate - Full Quality Assurance System

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

No. CE 673550
Issued To: Radley Scientific Ltd
Bremridge House
Ashburton
Devon
TQ13 7JX
United Kingdom

In respect of:

The design and manufacture of torsional ultrasonic devices for orthopaedic revision surgery.

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: **2019-10-09**

Date: **2019-10-09**

Expiry Date: **2024-05-26**

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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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Supplementary Information to CE 673550

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 1104, MDS 7010	Torsional Ultrasonic Devices	<p>The device is intended to be used for removal of polymethylmethacrylate (PMMA) bone cement in orthopaedic applications.</p> <p>The device is also intended to be used for cutting and cauterizing soft tissue during skin and muscle incision to access bone joints in limbs.</p>

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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:

Certificate No: **CE 673550**
 Date: **2019-10-09**
 Issued To: **Radley Scientific Ltd**
Bremridge House
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Devon
TQ13 7JX
United Kingdom

Subcontractor:

Service(s) supplied

Andersen-Caledonia
 Caledonian House
 Phoenix Crescent
 Strathclyde Business Park
 Bellshill
 North Lanarkshire
 Scotland
 ML4 3NJ
 UK

Control of Sterilization
ETO Sterilization

Granton Medical Ltd
 Parkway Close
 Parkway Ind. Est.
 Sheffield
 South Yorkshire
 S9 4WJ
 UK

Assembly
Labelling
Other Critical Processes
Packaging
Secondary Packaging

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Subcontractor:

Service(s) supplied

IlluminOss Medical GmBh
Muhlenhoff 7-9
Hilden
40721
Germany

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 673550**
Date: **2019-10-09**
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Date	Reference Number	Action
Current	8733568	First issue.

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