

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

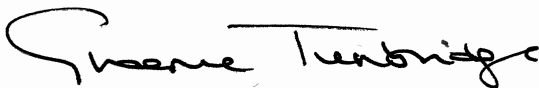
No. UKCA 768041
Issued To: Radley Scientific Ltd
Bremridge House
Ashburton
Devon
TQ13 7JX
United Kingdom

In respect of:

The design, manufacture and final inspection of sterile and non-sterile torsional ultrasonic devices for orthopaedic revision surgery.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-07-13**

Date: **2022-07-13**

Expiry Date: **2024-10-08**

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Supplementary Information to UKCA 768041

Issued To:

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Device code	Device name	Intended purpose per IFU
Class IIb		
MD 1104, MDS 7010	Torsional Ultrasonic Devices	<p>The device is intended to be used for removal of polymethacrylate (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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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

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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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Certificate History

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United Kingdom**

Date	Reference Number	Action
Current	3643635	First Issue; Traceable to CE 673550

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