

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 739879 R000

**Manufacturer:** Bradshaw Medical, Inc.

**Address:**

10325 - 58th Place  
Kenosha  
Wisconsin  
53144  
USA

**Single Registration Number:** US-MF-000003392

**EU Authorised Representative:** Emergo Europe B.V.

**Address:**

Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-09-16**

Date: **2021-09-16**

Expiry Date: **2026-09-15**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable Surgical Instruments 'Orthopaedic Instruments'	Class Ir
Reusable Surgical Instruments 'Neurosurgical Instruments'	Class Ir

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.



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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	3340972	Issued



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## List of Critical Subcontractors and Crucial Suppliers

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

### MDR 739879 R000

Date: 2021-09-16

Critical Subcontractor/Crucial Supplier	Service(s) supplied
IN'TECH MEDICAL SA 158 rue de l'Eglise 62180 RANG DU FLIERS France	Finished Device Supplier Manufacture

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