

EU Quality Management System Certificate

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

MDR 774956 R000

Manufacturer: Innovative Design Orthopaedics Limited

Address:

6 Brewery Court
Theale
Reading
Berkshire
RG7 5AJ
United Kingdom

Single Registration Number: GB-MF-000026411

EU Authorised Representative: MedNet EC-REP GmbH

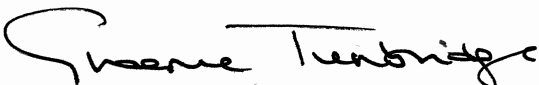
Address:

Borkstraße 10
48163 Münster
Germany

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-05-05**

Current Issue Date: **2023-05-05**

Starting Validity Date: **2023-05-05**

Expiry Date: **2028-05-04**

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

| Device(s) | Risk Classification |
|---|---------------------|
| Orthopaedic and traumatological surgery instruments, reusable | 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 | 3718169 | Issued |



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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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