EU Quality Management System Certificate

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

MDR 729135 R000

Manufacturer: Inion Oy

Address:
Laakarinkatu 2
Tampere
33520
Finland

Single Registration Number: FI-MF-000000646

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):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-06-22**

Current Issue Date: **2023-02-01**

Starting Validity Date: **2023-02-01**

Expiry Date: **2027-06-21**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Inion Hexalon™ Bioabsorbable Interference Screw	See MDR 734321
Inion CPS™ Bioabsorbable Fixation and Inion CPS™ Baby Bioabsorbable Fixation System	See MDR 761974

Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable instruments 'Orthopaedic Instruments'	Class Is
Reusable instruments 'Orthopaedic Instruments'	Class Im
Reusable instruments 'Orthopaedic Instruments'	Class Ir
Reusable instruments 'Orthopaedic Instruments'	Class Ir, Class Im
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements. 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
2022-06-22	3207477	Issued
Current	3814626	Supplemented – Addition of Inion CPS™ Bioabsorbable Fixation and Inion CPS™ Baby Bioabsorbable Fixation System

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