EU Quality Management System Certificate

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

MDR 724378 R001

Manufacturer: Enztec Limited

Address:
3/17 Print Place
Middleton
Christchurch
8024
New Zealand

Single Registration Number: NZ-MF-000002264

EU Authorised Representative: Advena Limited

Address:
Tower Business Centre, 2nd Flr.,
Tower Street
Swatar, BKR 4013
Malta

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 Global Regulatory & Quality

First Issue Date: **2020-08-06**

Current Issue Date: **2025-07-29**

Starting Validity Date: **2025-08-06**

Expiry Date: **2030-08-05**

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

Device(s)	Risk Classification
Orthopaedic instruments connected to an active device - Reusable Surgical Instruments	Class IIa
Orthopaedic implant trials – Reusable Surgical Instruments	Class IIa
Reusable instruments "Orthopaedic instruments"	Class Ir
Reusable instruments "Orthopaedic instruments"	Class Ir, Class Im
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
2020-08-06	3147250	First Issue
2020-10-19	3312997	Supplemented – Addition of Class IIa 'Orthopaedic instruments connected to an active device – Reusable Surgical Instruments' to the device schedule
2022-07-12	3541701	Supplemented – Addition of Class IIa 'Orthopaedic implant trials – Reusable Surgical Instruments' to device schedule Amended – Administrative update to device schedule changing 'Class Ir & Im' to 'Class Ir, Class Im' Amended – Administrative update to change 'Reusable surgical instruments "Orthopaedic Instruments" ' to 'Reusable instruments 'Orthopaedic Instruments' ' Amended – Administrative update to the 19 October 2020 Action in the Certificate History to correct the description of the devices to 'Orthopaedic instruments connected to an active device – Reusable Surgical Instruments' Amended – Addition of SRN NZ-MF-000002264 to manufacturer details Amended – correction of date format for all preceding certificate history entries, to align with BSI policy
Current	30408399	Re-Issued – Certificate Renewal

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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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