Number: 2250004CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Bioretec Ltd.

Yrittäjänkulma 5
33710 Tampere
Finland
SRN ID.: FI-MF-000000328

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2094913CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **7 October 2022** Date: **29 January 2025** Expiry date**: 1 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

2184-4

Number: 2250004CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable instruments (MDN 1208, class Ir)
Reusable Surgical Instruments – Surgical instruments for Orthopaedic Implants

Class III
Device Name: RemeOs Screw

Conditions for or limitations to the validity of this certificate:

- 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, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	7 October 2022	2094913CN26	First issue
1	29 January 2025	2094913CN28	Revised

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