

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 652848
Issued To: Enztec Limited
3/17 Print Place
Middleton
Christchurch
8024
New Zealand

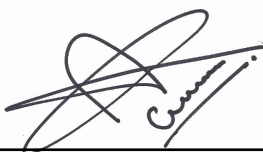
In respect of:

Design, development and manufacture of single use instruments, instrumentation for connection to active devices, and trials to be end user sterilised for use in the field of orthopaedics

Those aspects of Annex II relating to the accuracy of metrology in the design and manufacture of surgical instruments

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Albert Roossien, Regulatory Lead

First Issued: **2016-09-29**

Date: **2019-02-20**

Expiry Date: **2020-10-16**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Priory Analysts Ltd
Mazars, The Pinnacle
160 Midsummer Boulevard
Milton Keynes
MK9 1FF
United Kingdom

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 652848**
 Date: **2019-02-20**
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Date	Reference Number	Action
29 September 2016	8520335	First issue Transfer from another Notified Body.
13 March 2018	8844518	Extension to scope to include "Those aspects of Annex II relating to the accuracy of metrology in the design and manufacture of surgical instruments"
Current	8870982	Traceable to NB 0086.

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