

# 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**  
**26 Dakota Crescent**  
**Sockburn**  
**Christchurch**  
**8042**  
**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**

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **29 September 2016**

Date: **29 September 2016**

Expiry Date: **16 October 2020**

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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.

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## List of Significant Subcontractors

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

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Sockburn  
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8042  
New Zealand**

**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: **29 September 2016**  
 Issued To: **Enztec Limited  
 26 Dakota Crescent  
 Sockburn  
 Christchurch  
 8042  
 New Zealand**

Date	Reference Number	Action
29 September 2016	8520335	First issue Transfer from another Notified Body.

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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.  
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