

# EC Certificate - Full Quality Assurance System

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

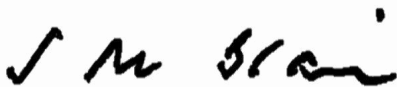
**No.** CE 662059  
**Issued To:** **Senzime AB**  
**31 Braintree Business Park**  
**Blackwell Drive**  
**Braintree**  
**CM7 2PU**  
**United Kingdom**

In respect of:

**The design and manufacture of electromyography based neuromuscular stimulators and monitors.**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-12-11**

Date: **2017-12-11**

Expiry Date: **2022-12-10**

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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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**CM7 2PU**  
**United Kingdom**

**Subcontractor:**

**Service(s) supplied**

Medical Device Management Ltd  
31 Braintree Business Park  
Blackwell Drive  
Braintree  
Essex  
CM7 2PU  
United Kingdom

**Design**  
**Manufacture**

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## Certificate History

Certificate No: **CE 662059**  
 Date: **2017-12-11**  
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Date	Reference Number	Action
11 December 2017	8620597	First Issue.

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