

# EC Certificate - Full Quality Assurance System

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

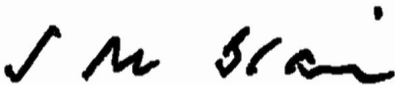
**No.** **CE 682840**  
**Issued To:** **Atlantic Therapeutics Ltd**  
**Parkmore Business Park West**  
**Galway**  
**H91 NHT7**  
**Ireland**

In respect of:

**The design and manufacture of neuro-muscular stimulation and rehabilitation devices for treatment of incontinence.**

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: **2018-01-25**

Date: **2018-01-25**

Expiry Date: **2023-01-24**

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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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**Subcontractor:**

**Service(s) supplied**

JDI Electronics Factory  
Sima Industrial Zone, Sima Village  
Chang Ping Town  
Dongguan  
Guangdong  
523570  
China

**Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 682840**  
 Date: **2018-01-25**  
 Issued To: **Atlantic Therapeutics Ltd  
 Parkmore Business Park West  
 Galway  
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 Ireland**

Date	Reference Number	Action
Current	8849561	First Issue



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