

# EC Certificate - Full Quality Assurance System

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

**No.****CE 646245****Issued To:**

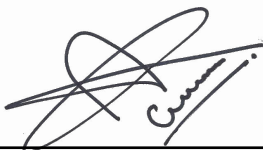
**Actegy Ltd.  
REFLEX  
Cain Road  
Bracknell  
Berkshire  
RG12 1HL  
United Kingdom**

In respect of:

**Design and manufacture of electrical muscle stimulators for treatment of circulatory disorders of the lower limbs and transcutaneous electrical nerve stimulators (TENS) for the treatment of pain.**

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: **2016-03-07**

Date: **2019-01-08**

Expiry Date: **2023-12-23**

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Page 1 of 2

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.

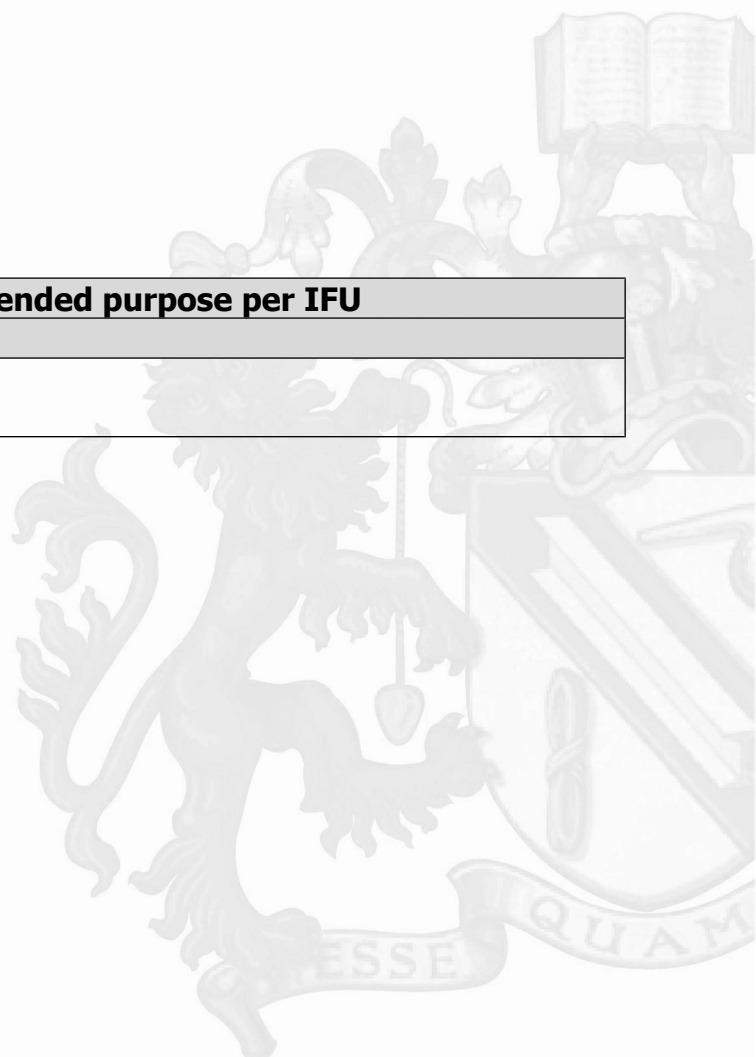
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## Supplementary Information to CE 646245

Issued To:

**Actegy Ltd.  
REFLEX  
Cain Road  
Bracknell  
Berkshire  
RG12 1HL  
United Kingdom**

Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1103	Devices for stimulation or inhibition.	---

First Issued: **2016-03-07**Date: **2019-01-08**Expiry Date: **2023-12-23**

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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:

Certificate No: **CE 646245**  
 Date: **2019-01-08**  
 Issued To: **Actegy Ltd.  
 REFLEX  
 Cain Road  
 Bracknell  
 Berkshire  
 RG12 1HL  
 United Kingdom**

### Subcontractor:

### Service(s) supplied

Mirae Medi & Tech Co. Limited  
 22, Baekseokgongdan 5-gil,  
 Seobuk-gu, Cheonan-si  
 Chungcheongnam-do  
 331220  
 South Korea

**Design  
 Manufacture**

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# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 646245**  
Date: **2019-01-08**  
Issued To: **Actegy Ltd.  
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Cain Road  
Bracknell  
Berkshire  
RG12 1HL  
United Kingdom**

Date	Reference Number	Action
07 March 2016	8441533	First Issue- Transfer from another notified body.
23 November 2016	8647046	Extension to scope to include "and transcutaneous electrical nerve stimulators (TENS) for the treatment of pain."
24 December 2018	9700285	Certificate Renewal.
Current	9715580	Traceable to NB 0086.

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