By Royal Charter

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**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

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
Class IIa		
MD 1103	Devices for stimulation or inhibition.	---

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

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 646245**
Date: **2019-01-08**
Issued To: **Actegy Ltd.**
REFLEX
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.