

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.
1 West Point, Western Road
Bracknell
Berkshire
RG12 1HJ
United Kingdom**

In respect of:

Design and manufacture of electrical muscle stimulators and software 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-03-07**

Date: **2021-05-14**

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.
1 West Point, Western Road
Bracknell
Berkshire
RG12 1HJ
United Kingdom

Number	Device Name or Device Subcategory	Intended purpose per IFU
Class IIa		
MD 1103	Devices for stimulation or inhibition.	N/A
MD 1111	Software for remote control of devices for stimulation or inhibition.	N/A

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Page 2 of 2

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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: **2021-05-14**
 Issued To: **Actegy Ltd.**
1 West Point, Western Road
Bracknell
Berkshire
RG12 1HJ
United Kingdom

Subcontractor:

Service(s) supplied

Actegy Ltd
 The Lightbox
 Willoughby Road
 Bracknell
 Berkshire
 RG12 8FB
 United Kingdom

**Design
 Development**

MDSS GmbH
 Schiffgraben 41
 30175 Hannover
 Germany

EU Representative

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

**Design
 Manufacture**

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Berkshire
RG12 1HJ
United Kingdom

Subcontractor:

Service(s) supplied

Pro4People Sp. z o.o.
 ul. Wołowska 18
 51-116 Wrocław
 Poland

Software

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Certificate History

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Date: **2021-05-14**
Issued To: **Actegy Ltd.**
1 West Point, Western Road
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RG12 1HJ
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.
08 January 2018	9715580	Traceable to NB 0086.
05 March 2021	3330446	Addition of EUAR – MDSS GmbH. Addition of Critical Subcontractor - Pro4People Sp. z.o.o. LM Address changed from: REFLEX, Cain Road, Bracknell, Berkshire, RG12 1HL, United Kingdom. To: 1 West Point, Western Road, Bracknell, Berkshire, RG12 1HJ, United Kingdom.

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Page 1 of 2

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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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Certificate History

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Date	Reference Number	Action
		Scope amended from: 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. To: Design and manufacture of electrical muscle stimulators and software for treatment of circulatory disorders of the lower limbs and transcutaneous electrical nerve stimulators (TENS) for the treatment of pain. Update of the device table to add "Software for remote control of devices for stimulation or inhibition."
Current	3430936	Addition of new location for design and development as: Actegy Ltd, The Lightbox, Willoughby Road, Bracknell, Berkshire, RG12 8FB.

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Page 2 of 2

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