actegy®
health powered by science
inspired by you™

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

EC DECLARATION OF CONFORMITY

I, the undersigned, hereby declare that the Class IIa medical devices specified below, conforms with the Essential Requirements listed in Annex I of EC Directive 93/42/EEC, as amended.

MODEL	PRODUCT DESCRIPTION	PRODUCT CODE
2837AB	Advanced Plus	3190
2837AB	Medic Pharma + (Australia)	2940
2837AB	Medic Pharma (France, BENELUX)	3183
2837AB	Medic Pharma (France, BENELUX)	4441
3156AD	Revitive Medic (New and improved) UK	3189
3156AD	Revitive Medic (New and improved) UK	4467
3156AD	Revitive Medic Plus (France, BENELUX)	4419
3156AD	Revitive Medic Plus (Germany)	4477
3156AD	Revitive Medic Plus (Australia)	4484

This declaration is made under Annex II (excluding Section 4) of EC Directive 93/42/EEC, as amended, under the supervision of Notified Body No 2797 – BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

As required in Article 14.2 and Article 1.2 (j) of the EC Directive 93/42/EEC, as amended Actegy Ltd has designated as its Authorised Representative **MDSS**, Schiffgraben 41, 30175 Hannover, Germany

Signed ..... Date .....09-JAN-2019.....
Lawrence Brookfield
Quality and Quality Manager

T +44 (0)1344 636 940 | F +44 (0)8452 255 612 | www.actegy.com

SCHEDULE OF STANDARDS APPLIED:

BS EN ISO 13485:2012 – Medical devices. Quality management systems – Requirements for regulatory purposes

BS EN ISO 9001:2015 – Quality management systems – Requirements

BS EN ISO 14971:2012 – Medical Devices – Application of risk management to medical devices

BS EN ISO 15223-1:2016 – Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

BS EN 1041:2008 – Information supplied by the manufacturer of medical devices

BS EN ISO 10993-1:2009 – Biological evaluation of medical devices – Part 1. Evaluation and testing

BS EN ISO 10993-5: 2009 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

BS EN ISO 10993-10:2013– Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

BS EN ISO 14155:2011 – Clinical investigation of medical devices for human subjects. General requirements

BS EN 62304:2006 – Medical device software. Software life-cycle processes

BS EN 62366-1:2015 – Medical devices. Guidance on the application of usability engineering to medical devices

BS EN 60601-1-6: 2010+A1:2015 – Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability

BS EN 60601-1:2006+A2:2014 – Medical Electrical Equipment. Part 1: General Requirements for Safety and Essential Performance

BS EN 60601-1-11:2015 – Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

BS EN 60601-2-10:2015 – Medical Electrical Equipment. Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators

BS EN 60601-1-2:2015– Medical Electrical Equipment. Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Revision History:

Version	Date	Description of Change
1.0	09Jan2019	Initial Issue

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**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 646245

Issued To:

Actegy Ltd.
REFLEX
Cain Road
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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**

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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**

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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.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: **MD 646246**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and Manufacture of electrical muscle stimulators, transcutaneous electrical nerve stimulators (TENS) and electronic respiratory muscle trainers.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-03-07
Latest Revision Date: 2019-02-28

Effective Date: 2019-03-01
Expiry Date: 2022-02-28

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UKAS MANAGEMENT SYSTEMS 003