actegy health powered by science inspired by you™

Actegy Ltd.
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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	Revitive Medic Pharma	3183

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 0086 – BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP

Signed ..... Date 25 April 2018.
Lawrence Brookfield
Global Quality and Regulatory Manager

SCHEDULE OF STANDARDS APPLIED:

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

EN ISO 9001:2015 Quality management systems – Requirements

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

ISO15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

EN 980:2008 Symbols for use in the labelling of medical devices

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

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

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

EN ISO 10993-10:2010 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 62366:2008 Medical devices. Application of usability engineering to medical devices.

BS EN 62304:2006+AC:2008 Medical device software. Software life-cycle processes

BS EN 60529:1992+A2:2013 Degrees of protection provided by enclosures (IP Code)

BS EN 60601-1:2006/A1:2013 Medical Electrical Equipment. Part 1: General Requirements for Safety and Essential Performance

BS EN 60601-1-11:2010 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 60601-2-10:2012 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	20Oct2017	Initial Issue