Actegy Ltd.
1 West Point
Western Road
Bracknell
Berkshire, RG12 1HJ
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 31-January-2022
Lawrence Brookfield
Quality and Regulatory Manager

T +44 (0)1344 636 940 | E info@uk.actegy.com | www.actegy.com

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SCHEDULE OF STANDARDS APPLIED:

BS EN ISO 13485:2016 – Medical devices. Quality management systems – Requirements for regulatory purposes

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

BS EN ISO 14971:2019 – 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 ISO 20417: 2021 – Medical devices - Information to be supplied by the manufacturer

BS EN ISO 10993-1:2020 – 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 14155:2020 – Clinical investigation of medical devices for human subjects. General requirements

BS EN 62304:2006+ A1: 2015 – Medical device software. Software life-cycle processes

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

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

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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

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Revision History:

Version	Date	Description of Change
1.0	09 Jan 2019	Initial Issue
2.0	31 Jan 2022	Updates to EN ISO 14971, EN 1041, EN ISO 10993-1, and EN ISO 14155 standards.

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