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:

- Directive 93/42/EEC concerning medical devices.
- Directive 2011/65/EU of the European parliament and of the Council 8 June 2011 on the Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoH-2).
- REACH EC 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- WEEE Directive, Directive 2012/19/EU of The European Parliament and of the Council Of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast)
- RED Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

MODEL	PRODUCT DESCRIPTION	PRODUCT CODE
5574AQ	Revitive Medic Knee (UK)	5606
5574AQ	Revitive Medic Knee (Germany)	6839
5574AQ	Revitive Medic Genou (France)	6157

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 05-March-2021
Lawrence Brookfield
Quality and Regulatory Manager

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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 14971:2012 – 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+A1:2013 – 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 60601-1-6: 2010+A1:2015 – Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability

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

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 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

FCC Part 47 CFR 15 - Federal Communication Commission (FCC) Part 47 Code of Federal Regulations, Part 15 Subpart B.

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Revision History:

Version	Date	Description of Change
1.0	09 April 2020	Initial Issue
2.0	05 March 2021	Addition of French and German versions

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