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

EC DECLARATION OF CONFORMITY

SRN (Single Registration Number): To Be Determined

Authorized Representative Name: Medical Device safety Service **(MDSS)**

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI 00858058005047

PRODUCT DESCRIPTION	PRODUCT CODE
Revitive Aerosure – UK	3465
Revitive Aerosure – Germany	4619
Revitive Aerosure – France/Benelux	4415
Revitive Aerosure - Australia	3479

Classification: I

Notified Body Name: British Standards Institution (BSI).

Notified Body Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body Identification Number: 2797

Conformity Assessment Route: Actegy Ltd uses the following procedures for the CE-marking of their products according to the Regulation MDR 2017/745:

Class I: EC conformity declaration according to Annex II and Annex III

This declaration of conformity is issued under the sole responsibility of Actegy Ltd. We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by the British Standards Institution (BSI).

All supporting documentation is retained at the premises of the manufacturer

Signed …….
Lawrence Brookfield
Quality & Regulatory Manager

Date: 25-May2021

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SCHEDULE OF REGULATIONS AND STANDARDS APPLIED:

- **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)

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

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 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 60601-1-2:2015– 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	25 May 2021	Initial Issue

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