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

EC DECLARATION OF CONFORMITY

I, the undersigned, hereby declare that the Class I medical devices specified below, conforms with:

- All relevant provisions outlined in the Official Journal of the European Community Council 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).

PRODUCT DESCRIPTION	PRODUCT CODE
Revitive Aerosure – UK	3465
Revitive Aerosure – Germany	4619
Revitive Aerosure – France/Benelux	4415
Aerosure Medic	1500

This declaration is made under Annex VII of EC Directive 93/42/EEC as amended.

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 .....
Lawrence Brookfield
Quality & Regulatory Manager

Date 03-JUL-2019

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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 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

Revision History:

Version	Date	Description of Change
1.0	21 Feb 2013	Initial Issue
2.0	16 Mar 2015	Update product codes. Addition of Canada, Benelux, German and Scandinavian.
3.0	01 Apr 2019	Aerosure Medic (UK) product code changed from 1307 to 3465, Aerosure Medic – French/Benelux changed from 2456 to 4415. Aerosure Medic – Scandinavia, Aerosure Sport – UK and Aerosure Sport – Scandinavia removed.
4.0	07 May 2019	Declaration made specific for Germany. Reference to Notified Body removed from page 1. Declaration changed from "...made under Annex II (Excluding section 4..." to "...made under Annex VII.." on page 1"
5.0	22 May 2019	Product Description and Product Code corrected for German device. Product Code changed from '4619' to '3481AJ' and Product Description from 'Aerosure Medic' to 'Revitive Aerosure'.
6.0	02 Jul 2019	Product Description for UK and France/Benelux changed from Revitive Medic to Revitive Aerosure. Product Code for Germany changed from 3481AJ to 4619.
7.0	03 Jul 2019	Aerosure Medic for Canada (1500) added.