DECLARATION of CONFORMITY

We,
Jolife AB
Scheelevägen 17
Ideon Science Park
SE-22370 LUND
Sweden

declare under our sole responsibility that the

LUCAS 3 CHEST COMPRESSION SYSTEM
version 3.0 and 3.1

to which this declaration relates, is CE marked based on conformity with the following directive(s), as transposed into national legislation of EU member states where it is placed on the market.

- Medical Device Directive 93/42/EEC (MDD), amended by Directive 2007/47/EC, compliance route through Annex II (Full quality assurance system - excluding section 4).
- Machinery Directive 2006/42/EC (EHSR)
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- Restriction of Hazardous Substances Directive 2011/65/EU (RoHS 2) and Commission Delegated Directive (EU) 2015/863 (RoHS 3)
- Radio Equipment Directive 2014/53/EU (RED) - including the WiFi & Bluetooth Module: LM811 (marked COM811)

LUCAS 3 CHEST COMPRESSION SYSTEM is class IIB acc. to MDD 93/42/EEC Annex IX, rule 9. The GMDN code is 44780 "Electric cardiac resuscitator".

Intended use:
"LUCAS 3 Chest Compression System is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS must only be used in cases where chest compressions are likely to help the patient."

The company's quality system complies with the following standards or other named normative documents

- EN ISO 13485:2016
- FDA, USA 21 CFR part 820

The Quality Management System and the Design & Development File is regularly audited by Notified Body No. 2460, DNV Product Assurance AS.

The LUCAS 3 CHEST COMPRESSION SYSTEM complies with the following standards:

- EN (IEC) 60601-1:2006/A1:2013 (edition 3.1) Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- EN 60601-1:2006+A2:2021 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI ES 60601-1:2005+A1 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- CAN/CSA C22.2 NO. 60601-1:14 (R2018) Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- EN (IEC) 60601-1-2:2015 Electromagnetic disturbances - Requirements and tests
- EN 60601-1-2:2015+A1:2021 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN (IEC) 60601-1-6:2010+A2:2021 Usability
- EN (IEC) 60601-1-8/A1:2013 +A11:2017 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- EN (IEC) 60601-1-8:2007+A2:2021 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-12:2014, AMD1:2020 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- EN (IEC) 62133:2012 +CORR 1:2013 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- EN (IEC) 62366:2008 + A1:2015 Application of usability engineering to medical devices
- EN (IEC) 62366-1:2015+A1:2020 Application of usability engineering to medical devices
- EN 1789:2020 Medical vehicles and their equipment - Road ambulances
- EN 13718-1:2014 Medical vehicles and their equipment - Air ambulances Part 1: Requirements for medical devices used in air ambulances
- ETSI EN 300 328 v2.2.2 (2019-07) Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
- ETSI EN 301 489-1v2.2.3 (2019-11) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
- ETSI EN 301 489-17 V3.2.4 (2020:09) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

The supporting documentation required to demonstrate compliance with the requirements of the MDD 93/42/EEC is retained by the company and is available for inspection by relevant enforcement authorities.

A list of Accessories and Spare Parts is available on page 3 of this declaration.

Lund, date: 21/9 2022 Authority:

Sara Lindroth
Managing Director

LIST of ACCESSORIES & SPARE PARTS

The accessories and spare parts listed in the table below are included in this Declaration of Conformity for LUCAS CHEST COMPESSION SYSTEM:

Name
LUCAS Back Plate, slim
LUCAS Suction Cup
LUCAS Carrying Case, Hard Shell
LUCAS 3 Instructions for Use (regional versions)
LUCAS 3 v 3.1 Instructions for Use (regional versions)
LUCAS Battery, Dark gray
LUCAS Stabilization Strap
LUCAS Patient Straps
LUCAS Power Supply, MWB100024A, Art. No.: 300 000-00 (regional versions)
LUCAS Car Power Cable 12-28VDC
LUCAS Battery Charger
LUCAS Anti Slip; Slim Back Plate
LUCAS PCI Back Plate
LUCAS Bumper Integrated Shaft Seal, Black Pair