EC Certificate
Full Quality Assurance System

Certificate No.:
242481-2017-CE-NOR-NA-PS Rev. 5.0

Project No.:
PRJC-545541-2016-MSL-NOR

Valid Until:
7 July 2023

This is to certify that the quality system of:

JOLIFE AB
Scheelevägen 17
Ideon Science Park
SE-223 70 LUND
Sweden

For design, production and final product inspection/testing of:

Systems to be used in connection with resuscitation of persons who suffer from acute cardiac arrest

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 07 August 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Villy Rønneberg

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces DNV GL (NB 0434) certificate No. 200627-2016-CE-NOR-NA following transfer of notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-01
1.0	Corrected the validity end date	2017-11-28
2.0	Introducing version 3.1, and brand change to Stryker	2018-02-15
3.0	Removal of Lucas 1	2018-06-15
4.0	Re-certification	2018-07-06
5.0	Change of the scope of the EC certificate	2018-08-07

Products covered by this Certificate:

Product Description	Product Name	Class
Mechanical Chest Compression System	LUCAS® 2	IIb
	LUCAS® 2AD	
	LUCAS® 3	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Scheelevägen 17, Ideon Science Park, SE-223 70 Lund, Sweden

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242481-2017-CE-NOR-NA-PS Rev. 5.0	**PRJC-545541-2016-MSL-NOR**	**07 July 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

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).
- Machinery Directive 2006/42/EC (EHSR)
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- Restriction of Hazardous Substances 2 Directive 2011/65/EU (RoHS 2)
- Radio Equipment Directive 2014/53/EU (RED)

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 13485:2012
- ISO 13485:2003
- FDA, USA 21 CFR part 820

The Quality Management System and the Design & Development File is regularly audited by Notified Body No. 2460, DNV GL Nemko Presafe 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
- ANSI/AAMI ES 60601-1:2005(R)2012 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- CSA C22.2 No.60601-1:14 (3rd edition) 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 (IEC) 60601-1-6/A1:2015 Usability
- EN (IEC) 60601-1-8/A1:2013 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-12:2014 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- EN (IEC) 62133:2012 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 Application of usability engineering to medical devices
- EN 1789:2007 + A2:2014 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
- EN 300 328 v2.1.1 (2016-11) 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
- EN (ETSI) 301 489-1 v2.2.0 (2017-02) 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
- EN (ETSI) 301 489-17 v3.2.0 (2017-02) 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: 2018-05-07 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 3 CHEST COMPRESSION 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