

## **DECLARATION of CONFORMITY**

We, Jolife AB IDEON Science Park S-22370 LUND Sweden

declare under our sole responsibility that the product

## **LUCAS 2 Chest Compression System**

to which this declaration relates is in conformity with the following laws, standards or other named normative documents

MDD 93/42/EEC Medical Device Directive incl. 2007/47

The product complies with

- IEC60601
- CAN/CSA-C22.2 No. 601-1 M90
- UL 60601-1, 2003

The companys quality system complies with

- ISO13485
- FDA, USA 21 CFR part 820

The LUCAS 2 is a class IIb product according to MDD93/42/EEC

The intended use is:

 LUCAS Chest Compression System is to be used for performing external cardiac compressionson 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 technical documentation required to demonstrate that the product meets the requirements of the Medical Device Directive has been compiled by the company and is available for inspection by relevant enforcement authorities.

The list of accessories can be seen on page 3

Lund, date:

25 Nov 2010

Authority:

Erik von Schenck, Managing Director



## 1 List of Accessories

The accessories listed in the table below are included in this Declaration of Conformity for LUCAS 2:

Name	
LUCAS	S 2 Battery
LUCAS	S 2 Power Supply with cord
LUCAS	2 Car Cable
LUCAS	2 Suction Cup
LUCAS	2 PCI Back Plate
LUCAS	2 Back Plate Grip Tape
LUCAS	2 Stabilization Strap
LUCAS	2 Patient Straps
LUCAS	2 Carrying Bag