EU Declaration of Conformity TO MEDICAL DEVICE REGULATION 2017/745	
Legal Manufacturer Name	Jolife AB
Legal Manufacturer SRN	SE-MF-000002091
Legal Manufacturer Address	Jolife AB, Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden
Trade Name *(See Appendix A for detailed product information)*	LUCAS 3 version 3.1 Chest Compression System
We hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Devices Regulation 2017/745. Each of the CE-marked products in the appendix has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulations 2017/745 prior to being placed on the market. This Declaration of Conformity is valid in conjunction with the respective production release records for the referenced devices. This declaration applies to CE Marked devices produced after the date issuance of this declaration and before it is superseded by another declaration or withdrawn.	
We declare, under our sole responsibility, that the products specified in the product list also conform to the following regulations and directives. The batteries in Appendix B have been verified against defined criteria and found to be in compliance with EU Battery Regulation 2023/1542/EC.	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)
	EU Battery Regulation 2023/1542/EC
Name of Notified Body	DNV Product Assurance AS
ID Number of Notified Body	2460
Description of Conformity Assessment Procedure	Annex IX of Regulation (EU) 2017/745
Issued Certificate Number	10000473390-PA-NoMA-DNK
Reference to Common Specifications	N/A
The company's quality system complies with the following standards	EN ISO 13485: 2016
Additional Information	N/A

Issued by:	*Name and Signature:*	*Date:*
	Electronically signed by: Sara Lindroth *Reason: I am signing as the Author of this document* *Date: Aug 18, 2024 22:56 GMT+2* Sara Lindroth Managing Director, Jolife AB	18-Aug-2024 *Place:* Lund

Appendix A: Medical Devices

Product Trade Name	Catalogue Number	Jolife Part Number	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Device Nomenclature	CE TD Number	Initial CE release date
LUCAS 3, 3.1, IN SHIPPING BOX, INTL EN	99576-000064	160000-31	08858250000696SQ	IIb	Rule 9	The LUCAS Chest Compression System is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest, defined as the absence of spontaneous breathing and pulse as well as loss of consciousness. LUCAS must only be used in cases where chest compressions are likely to help the patient.	**EMDN Term / CND nomenclature:** Z120304 Cardiac Compressors **GMDN Code**: 44780 Electric cardiac resuscitator	AJE20190711-2	2018
LUCAS 3, 3.1, IN SHIPPING BOX, INTL EN, FR	99576-000065	160000-32							
LUCAS 3, 3.1, IN SHIPPING BOX, DA, SV, NO	99576-000069	160000-37							
LUCAS 3, 3.1, IN SHIPPING BOX, SV, FI	99576-000070	160000-38							
LUCAS 3, 3.1, IN SHIPPING BOX, IS	99576-000082	160000-39							
LUCAS 3, 3.1, IN SHIPPING BOX, DE	99576-000071	160000-40							
LUCAS 3, 3.1, IN SHIPPING BOX, DE, FR, IT	99576-000072	160000-41							

Product Trade Name	Catalogue Number	Jolife Part Number	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Device Nomenclature	CE TD Number	Initial CE release date
LUCAS 3, 3.1, IN SHIPPING BOX, DE, FR, NL	99576-000073	160000-42	08858250000696SQ	IIb	Rule 9	The LUCAS Chest Compression System is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest, defined as the absence of spontaneous breathing and pulse as well as loss of consciousness. LUCAS must only be used in cases where chest compressions are likely to help the patient.	**EMDN Term / CND nomenclature:** Z120304 Cardiac Compressors **GMDN Code**: 44780 Electric cardiac resuscitator	AJE20190711-2	2018
LUCAS 3, 3.1, IN SHIPPING BOX, IT, ES, PT	99576-000074	160000-43							
LUCAS 3, 3.1, IN SHIPPING BOX, PL	99576-000075	160000-44							
LUCAS 3, 3.1, IN SHIPPING BOX, ET, LV, LT	99576-000077	160000-46							
LUCAS 3, 3.1, IN SHIPPING BOX, HR, BG, RO, SL, SR	99576-000078	160000-47							
LUCAS 3, 3.1, IN SHIPPING BOX, CS, HU, SK	99576-000079	160000-48							
LUCAS 3, 3.1, IN SHIPPING BOX, EL, TR, HE	99576-000080	160000-49							

Appendix B: Batteries

Product name	Type	Jolife Part Number
LUCAS Battery, dark grey	Rechargeable Lithium Ion	160201-00

AFF20200507-1 Rev F LUCAS 3 version 3_1 Declaration of Conformity

Final Audit Report 2024-08-18

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