EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
LifeVac Europe Ltd.	Horswell Farm, Bishops Tawton, Devon, EX32 0ED, United Kingdom	GB-MF-000010279

AUTHORISED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
CMC Medical Devices & Drugs SL	C/ Horacio Lengo, N18, 29006, Málaga, Spain	ES-AR-000000293	+34951214054 info@cmcmedicaldevices.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalogue Number**	**Basic UDI-DI**
LifeVac Assembly Boxed	LV01	5065007352007
EMS LifeVac Assembly Bagged	LV07	5065007352014
Wall Mounted LifeVac Assembly	LV08	5065007352021
LifeVac Travel Kit	LV14	5065007352038
Intended Purpose		
LifeVac is a non-measuring, non-sterile, non-invasive, transient and single use, lifesaving apparatus, intended for clearing the airway of a choking patient when Basic Life Support (BLS) has been followed without success, or cannot be applied. The device is intended to be used by both healthcare professionals within a healthcare setting and laypersons outside of a healthcare setting.		

MDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	1 (self-certified)	Not Applicable
Rule	1	
EMDN:	R0599	Respiratory Devices, Suction and Dilation Systems – Other’
GMDN:	63287	Airway Emergency Clearance/ Suction Plunger’

LifeVac Europe Ltd declares that the above-mentioned products meet the provisions of the EU Medical Device Regulation (MDR) (EU) 2017/745.

Version Number:	10
Date Issued:	14-JUL-2023
Valid Until:	14-JUL-2026

Signed:	Eric Banagan (Jul 14, 2023 10:03 GMT+1)
Date:	14-JUL-2023
Name:	Eric Banagan
Role (Company):	Managing Director (LifeVac Europe Ltd.)

Appendix 1: Harmonized and other standards, European norms and guidance

Standards Number	Standards Organisation	Document Title
EN ISO 20417	BS EN	Information supplied by the manufacturer.
EN ISO 13485	BS EN	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14971	BS EN	Medical devices - Application of risk management to medical devices.
EN ISO 10993	BS EN	Biological evaluation of medical devices – Series.
EN ISO 4135	BS EN	Anaesthetic and respiratory equipment – Vocabulary.
EN ISO 15223-1	BS EN	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.