EC Declaration of Conformity

LifeVac – Class I Medical Device

Manufacturer:

LifeVac Europe Ltd
Horswell Farm
Bishops Tawton
Devon
EX32 0ED
UK

Authorised Representative

CMC Medical Devices
C/Horacio Lengo Nº 18
CP 29006,
Málaga-Spain
GB-MF-000010279

LifeVac is a non-sterile, 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.

In accordance with Annex IV of EU Medical Device Regulations (MDR 2017/745) and Annex VII of Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) , I, the undersigned, hereby declare that the Class I medical device specified below; is in conformity with the applicable provisions of the MDR 2017/745 and UK MDR 2002.

PRODUCT CODE	PRODUCT DESCRIPTION	UDI-DI
LV01	LifeVac Assembly Boxed	5065007352007
LV07	EMS LifeVac Assembly Bagged	5065007352014
LV08	Wall Mounted LifeVac Assembly	5065007352021
LV14	LifeVac Travel Kit	5065007352038

This Manufacturer self-certification, declaration of conformity, is made in accordance with Article 19 of the EU Medical Device Regulation 2017/745, having acted in accordance with the technical documentation requirements of Annexes II and III, as detailed in Article 52 (Point 7) for CE-Marking.
In addition, this declaration is made as a Manufacturer self-certification in accordance with the requirements of Part II of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002), for UKCA-marking.

Harmonised Standards Applied:
ISO 13485, ISO 14971, ISO 10993-1, BS EN ISO 10993-1, BS EN ISO 10993-5, BS EN ISO 10993-10, ISO 15223-1, ISO 20417 and ISO 14155.

Signed: ……

Date of Issue: ……16 January 2023……

Name: Eric Banagan

Role: Managing Director (LifeVac Europe Limited)

This Declaration of conformity is valid until 16th January 2026