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 single use lifesaving apparatus. Developed for clearing the airway of a choking victim 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 MDR 2017/745, I, the undersigned, hereby declare that the Class I medical device specified below; is in conformity with the applicable provisions of the EU Medical Device Regulations (MDR 2017/745).

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

Harmonised Standards:

EN ISO 14971, ISO 10993-1, BS EN ISO 10993-1, BS EN ISO 10993-5, BS EN ISO 10993-10, ISO 15223-1, BS EN 1041 and ISO 14155.

This declaration is made under Chapter II, Article 19 of MDR 2017/745, in conjunction with registration by the manufacturer with the UK Competent Authority and An Authorised EU Representative in accordance with Article 11 of the Regulation.

Signed: ..... Date of Issue: 20th June 2022

Name: Eric Banagan

Role: Managing Director (LifeVac Europe Limited)

This Declaration of conformity is valid until 1st July 2023