EC Declaration of Conformity

Manufacturers Name:	Kalogon, Inc.
Manufacturers Address:	2412 Irwin St, Melbourne, FL 32901, United States of America
Authorized Representative:	Easy Medical Device CommV
Authorized Representative Address:	Guldenberg 1 bus 2-4, 2000 Antwerpen, Belgium
SRN (Single Registration Number):	US-MF-000039535
Basic UDI-DI:	8600107425KAL-0501-S01E7
Name of the Device(s):	Sentinel
Classification:	I
Conformity assessment route:	Sentinel has been classified as Class I according to Annex VIII rule 13, and is in conformity with the general safety and performance requirements and provisions of the Regulation MDR 2017/745 and is in conformity with the relevant harmonized standards: ISO 14971: 2019 ISO 15223-1: 2021 ISO 13485: 2016 ISO 10993-1: 2018 IEC 60601-1-2: 2014 Medical electrical equipment. IEC 62304: 2006 IEC 62133-2: 2017 RoHS Directive 2011/65/EC; EMC Directive 2014/30/EU; Battery directive 2013/56/EU; Packaging Waste directive 94/62/EC; WEEE directive 2012/19/EU; General Product Safety Directive 2001/95/EC and is subject to the procedure set out in Annex II & III of the Regulation MDR 2017/745

Intended Use:
Sentinel is intended to maintain the internal air pressure of a single-chamber, vertical air cell cushion as set by a suitably experienced person.

When attached to a third-party cushion, it is capable of saving a desired air pressure value, and works to maintain the cushion at that value. As air-pressure and user weight change over time, Sentinel will routinely monitor these changes and correct cushion pressure as necessary. It further monitors for leaks in the cushion and can fill the cushion to counteract small leaks if they occur.

This declaration of conformity is issued under the sole responsibility of Kalogon Inc.
We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

DocuSigned by:
Tim Balz
66C339519107484……..…..
Kalogon CEO

Tim Balz

Place and date (dd.mm.yyyy) of issue:
Melbourne FL, US
06-12-2023

Place and date (dd.mm.yyyy):
Melbourne FL, US
06-12-2023

Attachment to declaration of conformity (Product reference list)

Product name	Article reference	Classification
Sentinel	KAL-0501-S01	Class I (rule 13)