

Number: 2246826CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Lode B.V.
Zernikepark 16
9747 AN Groningen
The Netherlands
SRN ID.: N/A

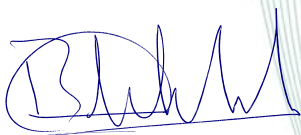
DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2110393CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Principal Certification Manager

First Issued: **3 January 2022**

Date: **25 March 2022**

Expiry date: **1 January 2027**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra-product-safety.com Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Active non-implantable devices for monitoring of vital physiological parameters (MDA0203, Class IIa)

Excalibur Sport with BPM
Excalibur Sport with SpO2
Excalibur Sport with BPM & SpO2
Excalibur Sport PFM with BPM
Excalibur Sport PFM with SpO2
Excalibur Sport PFM with BPM and SpO2
ECG Streamer (950920)

Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport (MDA 0313, Class Im)

Excalibur Sport
Excalibur Sport PFM

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Conditions for or limitations to the validity of this certificate:

- For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Date of Issue certificate	Certification Notice Reference	Action
03-01-2022	2110393CN12	First Issue
25-03-2022	2110393CN13	Revised

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