Lode B.V.
Zernikepark 16
9747 AN Groningen
The Netherlands

Tel.: 31-(0)50-5712811
Fax : 31-(0)50-5716746
V.A.T.no: NL008483280B01
E-mail: ask@lode.nl

CE

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MANUFACTURERS DECLARATION OF CONFORMITY

Product identification:

Product group:	Ergometers with and without built-in blood pressure monitor, stress Tables and ECG monitoring devices.
Brand:	Lode
Type:	Excalibur Sport (PFM), SpO2, Blood Pressure Measurement, ECG Streamer
Manufacturer:	Lode B.V. Zernikepark 16 9747 AN Groningen The Netherlands
Notified Body:	DEKRA Certification B.V.
Certificate no:	2246826CE01 / 2110393CE02

We hereby declare that the above mentioned devices with catalogue numbers listed in the annexed product list of this declaration are in conformity with the applicable provisions of Medical Devices Regulation (EU) 2017/745 and Restriction of the use of certain hazardous substances RoHS 3 (EU Directive 2015/863).

MDR CONFORMITY ASSESSMENT ROUTE ACCORDING TO ANNEX IX[1] .

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Declaration Number:	MDR – 6
Revision Date:	17-06-2025
Place:	Groningen, Netherlands
Name:	K. Brouwer
Position:	Managing Director
Company:	Lode B.V.
Date of issue:	17-06-2025
Place of issue:	Groningen, Netherlands

[1] EC Declaration of Conformity Full Quality Assurance System

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Annex product list (1/1)

To Manufacturers Declaration of Conformity Number MDR - 6

Revision Date 17-06-2025

Ergometers

Product name	Article number	Basic UDI-DI	Classification	First serial number	Last Serial Number
Excalibur Sport	965910	871752464965910VT	Class Im (using rule 13 of Annex VIII)	20220082	
Excalibur Sport with Blood pressure measurement	965910B	871752464965910BVD	Class IIa (using rule 10 of Annex VIII)	20220082	
Excalibur Sport with SpO2 (blood saturation)	965910S	871752464965910SWF	Class IIa (using rule 10 of Annex VIII)	20220082	
Excalibur Sport with Blood pressure measurement and with SpO2 (blood saturation)	965910SB	871752464965910SBZP	Class IIa (using rule 10 of Annex VIII)	20220082	
Excalibur Sport PFM	965920	871752464965920VW	Class Im (using rule 13 of Annex VIII)	20220041	
Excalibur Sport PFM with Blood pressure measurement	965920B	871752464965920BVJ	Class IIa (using rule 10 of Annex VIII)	20220041	
Excalibur Sport PFM with SpO2 (blood saturation)	965920S	871752464965920SWL	Class IIa (using rule 10 of Annex VIII)	20220041	
Excalibur Sport PFM with Blood pressure measurement and with SpO2 (blood saturation)	965920SB	871752464965920SBZW	Class IIa (using rule 10 of Annex VIII)	20220041	

On body sensors

Product name	Article number	Basic UDI-DI	Classification	First serial number	Last Serial Number
ECG Streamer	950920	871752464950920UG	Class IIa (using rule 10 and rule 11 of Annex VIII)	20220001	

[1] EC Declaration of Conformity Full Quality Assurance System