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

0344

MANUFACTURERS DECLARATION OF CONFORMITY

Product identification:

Product group:	Ergometers and Treadmills with and without built-in blood pressure monitor, stress Tables, Rehabilitation Software and Ergometry Software.
Brand:	Lode
Type:	Corival (Pediatric/Recumbent/OEM/cpet/rehab), Excalibur cpet, Excalibur Sport (PFM), Brachumera (2) Sport (PFM), Angio and MRI-ergometers, Valiant 2 (cpet (XL), rehab (XL), sport (XL), pediatric, Flow cpet, OEM) , Katana (XL), Stress Tables (all types), LCRM, LEM
Manufacturer:	Lode B.V. Zernikepark 16 9747 AN Groningen The Netherlands
Notified Body:	DEKRA Certification B.V.
Certificate no:	2110393CE01

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 Directive 93/42/EEC and Restriction of the use of certain hazardous substances RoHS 3 (EU Directive 2015/863).

MDD CONFORMITY ASSESSMENT ROUTE ACCORDING TO ANNEX II[1] .

Declaration Number:	27
Revision Date:	May 25, 2021
Name:	J.J.P. Wolters
Position:	Managing Director
Company:	Lode B.V.

1 EC Declaration of Conformity Full Quality Assurance System

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

Annex product list (1/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

Ergometers

Product name	Article number	Classification	First serial number	Last Serial Number
Corival cpet	960900	Class Im (using rule 12 of Annex IX)	20150001	
Corival cpet with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	960900	Class IIa (using rule 10 of Annex IX)	20150001	
Corival rehab	960901	Class Im (using rule 12 of Annex IX)	20150001	
Corival rehab with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	960901	Class IIa (using rule 10 of Annex IX)	20150001	
Corival pediatric	960903	Class Im (using rule 12 of Annex IX)	20170001	
Corival pediatric with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	960903	Class IIa (using rule 10 of Annex IX)	20170001	
Corival OEM	960912	Class Im (using rule 12 of Annex IX)	20150001	
Corival OEM with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	960912	Class IIa (using rule 10 of Annex IX)	20150001	
Corival Recumbent cpet	969900	Class Im (using rule 12 of Annex IX)	20170001	
Corival Recumbent cpet with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	969900	Class IIa (using rule 10 of Annex IX)	20170001	
Corival Recumbent rehab	969901	Class Im (using rule 12 of Annex IX)	20170001	
Corival Recumbent rehab with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	969901	Class IIa (using rule 10 of Annex IX)	20170001	

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

Annex product list (2/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

Ergometers

Product name	Article number	Classification	First serial number	Last Serial Number
Excalibur cpet	965900	Class Im (using rule 12 of Annex IX)	20210001	
Excalibur cpet with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	965900	Class IIa (using rule 10 of Annex IX)	20210001	
Excalibur Sport	965910	Class Im (using rule 12 of Annex IX)	20190001	
Excalibur Sport with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	965910	Class IIa (using rule 10 of Annex IX)	20190001	
Excalibur Sport PFM	965920	Class Im (using rule 12 of Annex IX)	20190001	
Excalibur Sport PFM with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	965920	Class IIa (using rule 10 of Annex IX)	20190001	
Brachumera Sport	925901	Class Im (using rule 12 of Annex IX)	20110001	
Brachumera Sport with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	925901	Class IIa (using rule 10 of Annex IX)	20110001	
Brachumera Sport PFM	925910	Class Im (using rule 12 of Annex IX)	20120001	
Brachumera Sport PFM with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	925910	Class IIa (using rule 10 of Annex IX)	20120001	
Brachumera Sport 2	965911	Class Im (using rule 12 of Annex IX)	20210001	
Brachumera Sport 2 with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	965911	Class IIa (using rule 10 of Annex IX)	20210001	
Brachumera Sport 2 PFM	965921	Class Im (using rule 12 of Annex IX)	20210001	
Brachumera Sport 2 PFM with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	965921	Class IIa (using rule 10 of Annex IX)	20210001	

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

Annex product list (3/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

Ergometers

Product name	Article number	Classification	First serial number	Last Serial Number
Angio cpet	967900	Class Im (using rule 12 of Annex IX)	20170001	
Angio cpet with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967900	Class IIa (using rule 10 of Annex IX)	20170001	
Angio rehab	967901	Class Im (using rule 12 of Annex IX)	20170001	
Angio rehab with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967901	Class IIa (using rule 10 of Annex IX)	20170001	
Angio cpet with static wall fixation	967902	Class Im (using rule 12 of Annex IX)	20170001	
Angio cpet with static wall fixation with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967902	Class IIa (using rule 10 of Annex IX)	20170001	
Angio cpet with el. adj.wall fixation	967903	Class Im (using rule 12 of Annex IX)	20170001	
Angio cpet with el. adj.wall fixation with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967903	Class IIa (using rule 10 of Annex IX)	20170001	
Angio cpet with automatic stand	967904	Class Im (using rule 12 of Annex IX)	20170001	
Angio imaging with automatic stand with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967904	Class IIa (using rule 10 of Annex IX)	20170001	
Angio imaging with fix.set for instr.rail	967905	Class Im (using rule 12 of Annex IX)	20170001	
Angio imaging with fix.set for instr.rail with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967905	Class IIa (using rule 10 of Annex IX)	20170001	

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

Annex product list (4/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

Ergometers

Product name	Article number	Classification	First serial number	Last Serial Number
Angio rehab with static wall fixation	967922	Class Im (using rule 12 of Annex IX)	20170001	
Angio rehab with static wall fixation with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967922	Class IIa (using rule 10 of Annex IX)	20170001	
Angio rehab with el. adj. wall fixation	967923	Class Im (using rule 12 of Annex IX)	20170001	
Angio rehab with el. adj. wall fixation with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967923	Class IIa (using rule 10 of Annex IX)	20170001	
Angio rehab with automatic stand	967924	Class Im (using rule 12 of Annex IX)	20170001	
Angio rehab with automatic stand with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967924	Class IIa (using rule 10 of Annex IX)	20170001	
Angio rehab with fix.set for instr.rail	967925	Class Im (using rule 12 of Annex IX)	20170001	
Angio rehab with fix.set for instr.rail with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967925	Class IIa (using rule 10 of Annex IX)	20170001	
Angio rehab with bed carrier	967927	Class Im (using rule 12 of Annex IX)	20210001	
Angio rehab with bed carrier with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967927	Class IIa (using rule 10 of Annex IX)	20210001	

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

Annex product list (5/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

STRESS TABLES (in combination with Angio Imaging)

Product name	Article number	Classification	First serial number	Last Serial Number
Angio Imaging with stress support radiology	967930	Class Im (using rule 12 of Annex IX)	20170001	
Angio Imaging with stress support radiology with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967930	Class IIa (using rule 10 of Annex IX)	20170001	
Angio Imaging with stress support radiology	967940	Class Im (using rule 12 of Annex IX)	20170001	
Angio Imaging with stress support radiology with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967940	Class IIa (using rule 10 of Annex IX)	20170001	
Angio Imaging with stress support radiology ultrasound	967931	Class Im (using rule 12 of Annex IX)	20170001	
Angio Imaging with stress support radiology ultrasound with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967931	Class IIa (using rule 10 of Annex IX)	20170001	
Angio Imaging with stress support radiology ultrasound	967941	Class Im (using rule 12 of Annex IX)	20170001	
Angio Imaging with stress support radiology ultrasound with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	967941	Class IIa (using rule 10 of Annex IX)	20170001	

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

Annex product list (6/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

MRI ergometers

Product name	Article number	Classification	First serial number	Last Serial Number
MRI Pedal	937901	Class Im (using rule 12 of Annex IX)	20100046	
MRI Push-pull	937902	Class Im (using rule 12 of Annex IX)	20100046	
MRI Up-down	937903	Class Im (using rule 12 of Annex IX)	20100046	
MRI Dorsal ankle flex	937904	Class Im (using rule 12 of Annex IX)	20100046	

Software

Product name	Article number	Classification	First serial number	Last Serial Number
Lode Ergometry Manager (LEM 10)				
Main Software	955900	Class Im (using rule 12 of Annex IX)	20140001	
Module Wingate plus	955915			
Module Export	955920			
Module Astrand	955916			
Module Architect	955921			
Lode Cardiac Rehabilitation Manager (LCRM)	950902	Class IIa (using rule 10 of Annex IX)	20150048	

Treadmills

Product name	Article number	Classification	First serial number	Last Serial Number
Flow cpet	938910	Class Im (using rule 12 of Annex IX)	20170001	
Flow cpet with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938910	Class IIa (using rule 10 of Annex IX)	20170001	
Flow rehab	938911	Class Im (using rule 12 of Annex IX)	20170001	
Flow rehab with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938911	Class IIa (using rule 10 of Annex IX)		
(Valiant /) OEM2	939910	Class Im (using rule 12 of Annex IX)	20151001	
(Valiant /) OEM2 with Blood pressure measurement and /	939910	Class IIa (using rule 10 of Annex IX)	20151001	

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

or with SpO2 (blood oxygen saturation)				

Annex product list (7/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

Treadmills

Product name	Article number	Classification	First serial number	Last Serial Number
Valiant 2 familiy				
Valiant 2 cpet	938900	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 cpet with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938900	Class IIa (using rule 10 of Annex IX)	20140001	
Valiant 2 rehab	938901	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 rehab with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938901	Class IIa (using rule 10 of Annex IX)	20140001	
Valiant 2 sport	938902	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 sport with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938902	Class IIa (using rule 10 of Annex IX)	20140001	
Valiant 2 rehab XL	938903	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 rehab XL with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938903	Class IIa (using rule 10 of Annex IX)	20140001	
Valiant 2 pediatric	938904	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 pediatric with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938904	Class IIa (using rule 10 of Annex IX)	20140001	
Valiant 2 cpet XL	938905	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 cpet XL with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938905	Class IIa (using rule 10 of Annex IX)	20140001	
Valiant 2 sport XL	938906	Class Im (using rule 12 of Annex IX)	20140001	
Valiant 2 sport XL with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	938906	Class IIa (using rule 10 of Annex IX)	20140001	

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

Annex product list (8/8)

To Manufacturers Declaration of Conformity Number 27

Revision Date May 25, 2021

Treadmills

Product name	Article number	Classification	First serial number	Last Serial Number
Katana Family				
Katana Sport 400 V	934900	Class Im (using rule 12 of Annex IX)	20130001	
Katana Sport 400 V with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	934900	Class IIa (using rule 10 of Annex IX)	20130001	
Katana Sport 200 V	934901	Class Im (using rule 12 of Annex IX)	20140001	
Katana Sport 200 V with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	934901	Class IIa (using rule 10 of Annex IX)	20140001	
Katana Sport XL 400 V	934930	Class Im (using rule 12 of Annex IX)	20130001	
Katana Sport XL 400 V with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	934930	Class IIa (using rule 10 of Annex IX)	20130001	
Katana Sport XL 200 V	934931	Class Im (using rule 12 of Annex IX)	20140001	
Katana Sport XL 200 V with Blood pressure measurement and / or with SpO2 (blood oxygen saturation)	934931	Class IIa (using rule 10 of Annex IX)	20140001	