CERTIFICATE

Number: 2278667

The management system of:

Lode Holding B.V.

Also trading as Lode B.V., ProCare B.V., Umaco B.V. aXtion B.V. and ProCare België B.V.
Zernikepark 16
9747 AN Groningen
The Netherlands

Manufacturer Facility Identifier F007718

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
Design, development, manufacturing, distribution and servicing of Ergometer, Treadmill, Stress Table devices and built in, attached or standalone sensors and supporting software for the areas of physical testing and (p)rehabilitation.

Distribution and servicing of medical measurement devices, related and standalone software, sensors and disposables in the areas of physical testing and (p)rehabilitation.

Certificate expiry date:	2027-09-01
Certificate effective date:	2024-09-04
Certified since:	2024-09-04

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager

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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https://www.dekra-checkme.com/org

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM