



MONARK EXERCISE

FOR LIFE AND PERFORMANCE

DECLARATION OF CONFORMITY SPORTS & MEDICAL

Manufacturer

Monark Exercise AB
556103-3449
Kroons väg 1
SE-786 33 VANSBRO
EUDAMED SRN: SE-MF-000041879

PRODUCT INFORMATION

Monark ergometer bikes are medical devices designed for precise measurement and control of workload in testing, training, research, and rehabilitation. These devices are used to assess and improve cardiovascular and muscular function in clinical environments, including hospitals, sports medicine clinics, universities, and research facilities.

MODEL NAME	ART NO.	CLASS
Cardio Care 827 E	90827	Ila
Ergomedic 828 E	90828	Ila
Ergomedic 874 E	90874	Ila
Ergomedic 891E Wingate Option	90891-2	Ila
Ergomedic 894 E Peak Bike	90894	Ila
Monark LC4	LC4-12	Ila
Monark LT2	LT2-12	Ila
LC6	LC6-13 NOVO	Ila
LC7 TT novo	LC7 TT	Ila
Compact Rehab 871 E	90871	Ila
Rehab Trainer 881 E	90881	Ila
Cardio Care 927 E	90927	Ila
Monark 928 E	90928-12	Ila
Ergomedic 939 E	90939 NOVO	Ila
Monark RT2	RT2-13	Ila
RC4	RC4-12	Ila
RC6	RC6 NOVO	Ila



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CONFORMITY AND CERTIFICATION

We, Monark Exercise AB, hereby declare that the products listed above comply with the applicable requirements of Council Directive 93/42/EEC (MDD). Monark Exercise AB has entered into a formal agreement with RISE Medical Notified Body AB (NB 3033), which assumes surveillance responsibility during the transition to Regulation (EU) 2017/745 (MDR). Our products are currently marked with CE0402 until full MDR certification is achieved.

TRANSITION TO MDR

We expect to complete the technical documentation for MDR in September 2025 and aim to achieve full MDR certification in accordance with the transitional provisions extending to December 31, 2027, and December 31, 2028, depending on the product classification.

APPLICABLE STANDARDS AND REGULATIONS

The products have been manufactured and inspected in accordance with the following harmonized standards:

ISO 13485:2016

ISO 20957-1

ISO 20957-5

IEC 60601-1

IEC 60601-1-2

IEC 60601-1-6

Vansbro, 2024-09-26

Daniel Mäkinen
CEO, Monark Exercise AB