

DECLARATION OF CONFORMITY

SPORTS & MEDICAL

MANUFACTURING COMPANY

Monark Exercise AB
Box 6
SE-786 21 VANSBRO
Sweden

Monark Exercise AB
Kroons väg 1
SE-786 33 VANSBRO
Sweden

MODEL NAME	ART. NO.	CLASS OF THE DEVICES
CardioCare 827 E	90827	Class IIa
Ergomedic 828 E	90828	Class IIa
Ergomedic 874 E	90874	Class IIa
Ergomedic 891E Wingate Option	90891-2	Class IIa
Ergomedic 894 E	90894	Class IIa
Monark LC4	LC4-12	Class IIa
Monark LT2	LT2-12	Class IIa
Compact Rehab 871 E	90871	Class IIa
Rehab Trainer 881E	90881	Class IIa
Cardio Care 927 E	90927	Class IIa
Monark 928 E	90928-12	Class IIa
RT2	RT2-13	Class IIa
RC4	RC4-12	Class IIa

INTENDED USE

For tests, training, rehabilitation and research to improve people's health

We the undersigned hereby declare under our sole responsibility that the device specified above conform to the applicable essential requirements of medical device, class IIa, with respect to the provisions stated in Annex V of Council Directive 93/42/EEC, as latest amended by Council Directive 2007/47/EC, the Swedish law 1993:584 and the Swedish Directive LVFS 2003:11.

We hereby also confirm that the listed product complies with the criteria in IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-6.

The product is in conformity with the basic requirements of the Radio Equipment directive 2014/53/EU.

The product is compliant with the following standards:

ISO 20957-1
ISO 20957-5
EN 61000-3-2

The quality system has been examined by RISE Research Institutes of Sweden AB, notified body No: 0402.

Vansbro 2019-10-11



Daniel Mäkinen
Manager Director