

DECLARATION OF CONFORMITY

MONARK MEDICAL TREADMILL

Manufacturing Company

Monark Exercise AB
Box 6
SE-780 50 VANSBRO
Sweden

Monark Exercise AB
Kroons Väg 1
SE-780 50 VANSBRO
Sweden

NAME	ART. NO.	CLASS OF THE DEVICE
Monark Medical Treadmill	TRM1-17	Medical Device Directive 93/42/EEC, Class IIa ISO 20957-1 EN 61000-3-2

INTENDED USE

Medical equipment for training, rehabilitation, tests and research.

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 comply with the criteria in: IEC 60601-1, IEC 60601-2 and IEC 60601-6. The quality system has been examined by RISE Research Institutes of Sweden AB, notified body No: 0402.

Vansbro 2017-10-04



Andreas Hedbom
Manager Director