

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

(Annex V of the directive 93/42/EEC on medical devices)

No. 153601

issued to

Monark Exercise AB
Kroons väg 1
SE-750 80 Vansbro
Sweden

We hereby certify that the Quality System of

Monark Exercise AB

for production, final inspection and marketing of
**ergometer bikes for active rehabilitation, training, fitness testing and
work test, with associated patient connected equipment for measuring
of heart rate**

medical devices in class IIA has been assessed with respect to the
conformity assessment procedure according to Annex V of Council
Directive 93/42/EEC on Medical Devices, as latest amended
by Council Directive 2007/47/EC, and found to comply with the
requirements.

The Council Directive 93/42/EEC is implemented in Swedish Law by the
national regulation LVFS 2003:11.

This certificate applies to activities performed at

Kroons väg 1, SE-750 80 Vansbro, Sweden

This certificate was originally issued on 25th March 2010 and remains valid until
12th of October 2020 provided that the conditions connected to this certificate are
fulfilled.

RISE Research Institutes of Sweden AB
Certification - Notified Body No. 0402

Lennart Aronsson

Karin Andresen

Certificate No.153601 | issue 10 | 2017-10-04

RISE Research Institutes of Sweden AB | Certification
Box 857, SE-501 15 Borås, Sweden
Phone: +46 10-516 50 00
certifiering@ri.se | www.ri.se



Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use RISE notified body identification number 0402 in conjunction with the CE-mark, on products covered by this certificate, provided that the conditions stated below are fulfilled:

- that surveillance audits are performed, with approved result;
- that the company notifies RISE on all modifications on the products, and that the company does not apply the CE-mark to any new or modified products without confirmation from RISE;
- that the company notifies RISE on all significant changes in the quality system, in its activities and/or organization
- that the certificate is not used in a misleading manner, e.g. in marketing activities.
- that the company notifies RISE about vigilance actions, if any.

Basis for certificate

- The documentation presented has been examined and assessed by RISE in accordance with LVFS 2003:11, annex 5.
- An initial audit and follow-up audits of the quality system at the company's premises in Vansbro has been performed by RISE.
- RISE file 7P06676.

Surveillance

RISE will perform surveillance inspections to ensure that the company maintains and applies the quality system that is subject of the certificate.

In accordance with the EU Commission recommendations of 2013-09-24, there will also be unannounced audits once per every three years. These audits can be performed at the manufacturers as well as at selected crucial supplier's premises.

Miscellaneous

Additional conditions appear in "Terms and conditions for audit and assessment of management systems as notified body" and in Agreement concerning continuous inspection between Monark Exercise AB and RISE.

Certificate history

Issue	Date	Activity
1	25 th March 2010	Certificate issued
2	9 th July 2010	Certificate revised and extended: Product Cardio Care 837E added to the list
3	2 nd December 2011	Certificate revised and extended: Product Ergomedic 891 E Wingate Option added to the list
4	28 th May 2013	Certificate revised: Some product names changed, 8 products excluded
5	9th October 2013	Certificate revised and extended: Products Monark LC4/LC4r, Monark RT2, Monark LT2, Monark 928 G3/928 G3r, LC6/LC7 added to the list
6	24th March 2015	6 month prolonging of certificate
7	12 October 2015	Certificate re- issued
8	21 December 2015	Certificate revised; conditions changed

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9	13 February 2017	Certificate updated with details in the text, accreditation mark and new products
10	4 October 2017	New products added

Register of products covered by the certificate

Product	Art.no.	Class
Cardio Care 827 E		IIa
Cardio Care 927 E		
Cardio Care 927 X		
Ergomedic 891 E		
Compact Rehab 871 E		
Ergomedic 828 E		
Ergomedic 874 E		
Ergomedic 891 E Wingate Option		
Ergomedic 894 E Peak Bike		
Ergomedic 939 E		
Monark 915 E/970-9		
Rehab Trainer 881 E		
Monark LC4		
Monark RT2		
Monark LT2		
Monark 928 E		
LC6		
RC4		
RC6		
LC7 TT novo		
Medical Treadmill		

Note: New products in **bold**

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