



CERTIFIKAT

EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE
(Annex V of the directive 93/42/EEC on medical devices)

No. 15 36 01

issued to

Monark Exercise AB

Postal address:

Box 6, SE-780 50 Vansbro, Sweden

Street address:

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**

has been assessed with respect to the conformity assessment procedure
described in Article 11.2 (b) and 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.

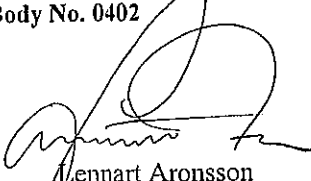
The Council Directive 93/42/EEC is implemented in Swedish Law by the
national regulation LVFS 2003:11, as latest amended by LVFS 2013:11.

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 25th March 2015
provided that the conditions connected to this certificate are fulfilled.

SP Technical Research Institute of Sweden
Certification - Notified Body No. 0402


Lennart Månsson
Certification Manager


Lennart Aronsson
Certification Officer

Certificate no 15 36 01, issue no 5, dated 9th October 2013, page 1(3)

SP Technical Research Institute of Sweden

Postal address	Phone / Fax	Reg. number	E-mail / Internet
SP	+46 10 516 50 00	556464-6874	info@sp.se
Box 857	+46 33 13 55 02		www.sp.se
SE-501 15 Borås			
SWEDEN			

Swedish Notified Bodies are appointed by SWEDAC, the Swedish Board for Accreditation and
Conformity Assessment, under the terms of Swedish legislation.
This certificate may not be reproduced other than in full, except with the prior written approval
by SP.



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EC CERTIFICATE No. 15 36 01

Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use SPs 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 SP 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 SP;
- that the company notifies SP on all significant changes in the quality assurance system, in its activities and/or organization;
- that the certificate is not used in a misleading manner, e.g. in marketing activities.

Basis for certificate

- The documentation presented has been examined and assessed by SP in accordance with LVFS 2003:11, as amended by LVFS 2013:11, annex 5, item 3.2.
- An initial audit and follow-up audits of the quality system at the company's premises in Vansbro has been performed by SP.
- SP file P907661.

Surveillance

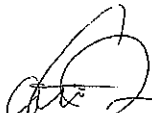
SP will perform surveillance inspections to ensure that the company maintains and applies the quality system that is subject of the certificate.

Miscellaneous

Additional conditions appear in "General certification rules for certification of products, CR000", and in Agreement concerning continuous inspection between Monark Exercise AB and SP.

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	9 th 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

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Register of products covered by the certificate

Designation	Classification
Cardio Care 827 E	IIa
Ergomedic 928 E	
Cardio Comfort 837 E	
Cardio Care 927 E	
Cardio Care 927 X	
Ergomedic 891 E	
Compact Rehab 871 E	
Ergomedic 828 E	
Ergomedic 839 E	
Ergomedic 874 E	
Ergomedic 891 E Wingate Option	
Ergomedic 894 E Peak Bike	
Ergomedic 939 E	
Monark 915 E/970-9	
Ergomedic 831 E	
Rehab Trainer 881 E	
Monark LC4/LC4r	
Monark RT2	
Monark LT2	
Monark 928 G3/928 G3r	
LC6/LC7	

Note: New items in this issue in bold

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