



# EC CERTIFICATE

## PRODUCTION QUALITY ASSURANCE SYSTEM CERTIFICATE

Cert no. 153601

issued to

### Monark Exercise AB

Kroons väg 1, 786 33 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 is implemented in Swedish Law by the national regulation LVFS 2003:11, and found to comply with the requirements

This certificate applies to activities performed at

**Kroons väg 1, SE-786 33 VANSBRO, Sweden**

Originally issued	2010-03-25
Decision date	2020-09-23
Expiry date	2024-05-26

Issued by Notified body 0402

Helén Dahl

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**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 V.
- 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 Ecert ID 67740

**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 "RISE General Terms - Assignment" and "Rules and process assessment of medical devices as notified body LVFS 2003:11".

**Certificate history**

Issue	Date	Activity
1	25 <sup>th</sup> March 2010	Certificate issued
2	9 <sup>th</sup> July 2010	Certificate revised and extended: Product Cardio Care 837E added to the list
3	2 <sup>nd</sup> December 2011	Certificate revised and extended: Product Ergomedic 891 E Wingate Option added to the list
4	28 <sup>th</sup> May 2013	Certificate revised: Some product names changed, 8 products excluded
5	9 <sup>th</sup> 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	24 <sup>th</sup> March 2015	6 month prolonging of certificate
7	12 October 2015	Certificate re- issued
8	21 December 2015	Certificate revised; conditions changed
9	13 February 2017	Certificate updated with details in the text, accreditation mark and new products
10	4 <sup>th</sup> October 2017	New products added
11	23 September 2020	Certificate revised and extended, productlist clarified: Cardio Care 927X, Ergonomic 891E, Monark 915E/970-9 has expired, name change of product Medical Treadmill to Monark Medical Treadmill

Register of products covered by the certificate

Product	Art.no	Class
Cardio Care 827 E	90827	Ila
Ergomedic 828 E	90828	Ila
Ergomedic 874 E	90874	Ila
Ergomedic 891 E 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
Monark Medical Treadmill	TRM1-17	Ila

Note: New products in **bold**