RISE Medical Notified Body Confirmation Letter

Monark Exercise AB
Kroons väg 1, 78633,
Vansbro
Sverige

26 September, 2024

RISE Medical Notified Body AB– Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, RISE Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 3033 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Monark Exercise AB
Kroons väg 1
786 33 Vansbro
Sverige

SRN Number (if available): SE-MF-000041879

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Sara Bergh
Enhetschef Certifiering

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Cardio Care 827E	Class IIa	N/A	153601
Ergomedic 828E	Class IIa	'N/A	153601
Ergomedic 874E	Class IIa	N/A	153601
Ergomedic 891E Wingate option	Class IIa	N/A	153601
Ergomedic 894E Peak Bike	Class IIa	N/A	153601
Monark LC4	Class IIa	N/A	153601
Monark LT2	Class IIa	N/A	153601
LC6	Class IIa	N/A	153601
LC7 TT novo	Class IIa	N/A	153601
Compact Rehab 871E	Class IIa	N/A	153601
Rehab Trainer 881E	Class IIa	N/A	153601
Cardio Care 927E	Class IIa	N/A	153601
Monark 928E	Class IIa	N/A	153601
Ergomedic 939E	Class IIa	N/A	153601
Monark RT2	Class IIa	N/A	153601
RC4	Class IIa	N/A	153601
RC6 NOVO	Class IIa	N/A	153601

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-09-26	1	Initial issue

Verifikat

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Dokument

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Signerare

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