EU Quality Management System Certificate

Certificate no.:
C639519

Initial certification date:
26 February 2026

Valid Until:
26 February 2031

This is to certify that the quality system of

MIR - Medical International Research S.p.A.

Viale Luigi Schiavonetti, 270-278,Int. 6 - Scala E,00173 Rome RM
SRN: IT-MF-000014026

For design, production, and final product inspection/testing of:
spirometry device with pulse oximetry function and software medical device.

Has been assessed and found to comply with respect to:
The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 13 March 2026

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

C. Rajesh Kumar

Rajesh Kumar Chellappan
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com
MDR-CO-078-A V0.8

Certificate no.: C639519
Place and date: Høvik,13 March 2026

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2985708	26 February 2026
1.0	Add new device and scope change	3014052	27 February 2026
2.0	Add new device	3014052	03 March 2026
3.0	Add new device and scope change and Admin change related to issue date	3033918	13 March 2026

Products covered by this Certificate:

Product Description	Product Name	Class*
Spirometers	Minispir Plus, Minispir Plus ESI	IIa
Spirometers with optional pulse oximeters	Spirobank II Plus, Spirobank II Light	IIa
Spirometers with optional pulse oximeters	Spirolab Plus, Spirolab Plus ESI	IIa
Medical device software for spirometry and oximetry	MIR Super SDK	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
MIR - Medical International Research S.p.A. Registered Office and Operational Site	Viale Luigi Schiavonetti, 270-278,Int. 6 – Scala E, 00173 Rome RM

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system

Terms and conditions

and the Notified Body will assess the changes and decide if the certificate remains valid.

- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.