



MDSAP CERTIFICATE

No. 002.22-3/MDSAP

This is to certify that

General Medical Merate S.p.A.

Main Site: Via Partigiani 25, Seriate, Bergamo, 24068, Italy

Facility ID: F006589

Refer to Attachment to Certificate of Registration for additional certified sites

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

United States:

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 - Subparts A to D
- 21 CFR Part 820

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

for the following scope of certification

Design, manufacture, final inspection, installation and servicing of x-ray equipment and systems for the area of radiology.

Reference to IMQ files Nos.:

DM22-0083734-01; DM22-0083743-01; DM23-0096265-01; DM24-0111330-01; DM25-0120799-01

Effective Date: 2026-01-23

Expiry Date: 2029-01-22

Issued on: 2026-01-09

IMQ

Matteo Raimondi – IMQ MDSAP Director



IMQ S.p.A. is an MDSAP Recognized Auditing Organization

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 002.22-3/MDSAP

Site address	Site scope
General Medical Merate S.p.A. Via Partigiani 25 Seriate, Bergamo, 24068, Italy Facility ID: F006589	Design, manufacture, final inspection, installation and servicing of x-ray equipment and systems for the area of radiology.
General Medical Merate S.p.A. Viale Unità d'Italia 40 Cassano Delle Murge, Bari, 70020, Italy Facility ID: F006590	Production of x-ray equipment and systems for the area of radiology.