



MDSAP CERTIFICATE

Certificate No. 002.22/MDSAP

This is to certify that

General Medical Merate S.p.A.

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

Facility ID: F004365

Refer to Attachment to Certificate of Registration dated January 10, 2023 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

Canada:

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

United States:

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

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

Original Certification Date:	2022-10-25
Issue Date:	2023-01-10
Certification Effective Date:	2023-01-23
Expiry Date:	2026-01-22

IMQ

Eng. Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 002.22/MDSAP issued on 2023-01-10

Site address	Site scope	Effective Date
General Medical Merate S.p.A. Via Partigiani 25 Seriate, Bergamo, 24068, Italy MDSAP Facility Identifier: F004365	Design, manufacture, final inspection, installation and servicing of x-ray equipment and systems for the area of radiology.	2023-01-23
General Medical Merate S.p.A. Viale Unità d'Italia 40 Cassano Delle Murge, Bari, 70020, Italy MDSAP Facility Identifier: F004374	Production of x-ray equipment and systems for the area of radiology.	2023-01-23