



## 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 October 25, 2022 for additional certified sites

Operates a

**Quality Management System, which complies with the requirements of ISO 13485:2016 and of 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 SOR/98-282, Part 1

**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

Issue Date:	2022-10-25
Certification Effective date:	2022-10-25
Expiry Date:	2023-01-22

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**IMQ**  
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 2022-10-25

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.	2022-10-25
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.	2022-10-25