

EU Quality Management System Certificate FI24/0000001

The management system of

# General Medical Italia LTD Swiss Branch

Piazzetta Luigi Fontana 4, 6850, Mendrisio, Switzerland  
SRN: CH-MF-000030023

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

For the following products and activities  
Digital radiography systems

### Issue 2

Previous certificate's number and issue: FI 24/0000001 Issue 1

Change in between this certificate and the previous one: Address and EU Authorized Representative changed

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 03 December 2025 until 09 January 2029 and remains valid subject to satisfactory surveillance audits.

Certified since 10 January 2024

Certified activities performed by additional sites are listed on the subsequent pages.



Authorised by  
Teuvo Vaara, Certifier

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**FINAS**  
Finnish Accreditation Service  
S009 (EN ISO/IEC 17021-1)

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# General Medical Italia LTD Swiss Branch

## Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

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| Issue 2   |
| <b>Sites</b>  |
| Main site 1<br>Piazzetta Luigi Fontana 4, 6850, Mendrisio, Switzerland                    |
| Design, development, distribution, sales and service of active non-implantable diagnostic |
| Site 2<br>Via Roncaglia 2, 6883 Novazzano, Switzerland                                    |
| Production  |

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# General Medical Italia LTD Swiss Branch

## Regulation (EU) 2017/745 Annex IX (I, III, and TDA in Section 4)

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| <b>Attachment 1 of Issue 2</b>   |
| <b>Risk classes, codes, identification, and other relevant details of the certified devices:</b>   |
| <p><b>Risk class IIb</b><br/>MDT 2010, MDT 2011, MDT 2012, MDA 0201, MDS 1004, MDS 1009<br/>EMDN Z11031101 Multifunctional Systems for Direct Digital Radiology<br/>X-ray radiographic system, Basic UDI-DI: 7649996713Lucerna-RF-FaVB, Model: Lucerna RF-TILT,<br/>Intended use: Digital medical X-ray radiographic system, which can be used for general, gastrointestinal x-ray fluoroscopy and image checking, to get images for clinical diagnostic use.</p> <p>X-ray radiographic system, Basic UDI-DI: 7649996713Lucerna-UA-FaV9, Model: Lucerna U-ARM,<br/>Intended use: Generation of radiographic and fluoroscopic images of human anatomy in all general purpose X-ray diagnostic procedures.</p> <p>X-ray radiographic system, Basic UDI-DI: 7649996713Geneve-40M-FaD4, Model: Genève 40 M,<br/>Intended use: Mobile X-ray radiography system with capabilities to take x-ray images of chest, abdomen, bone and soft tissues in medical institutions.</p> |
| <b>The certification decision is based on the following:</b>   |
| <p><b>Report Identification and Date:</b><br/>Audit report: GMI - V3 - 2024 - FPMDREG3019 - MD Audit Report Ver G, dated 2024-11-07</p> <p><b>Applied Standards / Common specifications:</b><br/>EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports</p> <p><b>Conditions for or limitation to the validity of the certificate:</b><br/>N/A</p> <p><b>EU Authorised Representative:</b><br/>SRN: IT-AR-000037736: Italian Radiology Industry srl, Via San Nicola, 24, 83042 Atripalda (AV), Italy</p>   |

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