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:
Digital radiography systems

Certification is based on decision FI24/08138P0
Previous certificate number: N/A
Change in between this certificate and previous one: N/A
Devices covered, their intended purposes, risk classification, 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 10 January 2024 until 09 January 2029 and remains valid subject to satisfactory surveillance audits.
Issue 1 Certified since 10 January 2024.
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Seppo Vahasalo, NB Manager

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

General Medical Italia LTD Swiss Branch

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Attachment 1 of Issue 1

EMDN Code	Risk Class	Identification Details and Intended Purposes
EMDN Z11031101 Multifunctional Systems for Direct Digital Radiology	IIb	Model: Lucerna RF-TILT Intended purpose: 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.
EMDN Z11031101 Multifunctional Systems for Direct Digital Radiology	IIb	Model: Lucerna U-ARM Intended purpose: Generation of radiographic and fluoroscopic images of human anatomy in all general purpose X-ray diagnostic procedures
EMDN Z11031101 Multifunctional Systems for Direct Digital Radiology	IIb	Model: Genève 40 M Intended purpose: Mobile X-ray radiography system with capabilities to take x-ray images of chest, abdomen, bone and soft tissues in medical institutions

The certification decision is based on the following:

Report Identification and Date
Audit report: MDR-2028 - GMI_V1-S2_FPMDREG3019 - MD Audit Report Ver E 20231228 dated 2023-12-28. Surveillance audit report: GMI - V2 - 2023 - FPMDREG3019 - MD Audit Report Ver E 20231111 dated 2023-11-11. TDA report: GMI - FPMDREG3020 - MDR Technical Documentation Assessment Report Ver E 20231228, dated 2023-12-28.

EU Authorised Representative
Wandong Medical Italia SRL Via Enrico.Fermi, 26 24050 Grassobbio (BG) Italy SRN: IT-AR-000037736