

Certificate FI23/00000057

The management system of

General Medical Italia LTD Swiss Branch

Piazzetta Luigi Fontana 4, 6850 Mendrisio, Switzerland

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design, development, production, distribution, sales and service of active non-implantable diagnostic imaging x-ray devices

The certified activity also meets the requirements of EN ISO 13485:2016/A11:2021.

This certificate is valid from 02 December 2025 until 20 November 2026 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 21 November 2023

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



Authorised by
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Certificate FI23/00000057, continued

General Medical Italia LTD Swiss Branch



ISO 13485:2016

EN ISO 13485:2016

Issue 2

Sites

General Medical Italia LTD Swiss Branch
Piazzetta Luigi Fontana 4, 6850 Mendrisio, Switzerland

Design, development, distribution, sales and service of active non-implantable diagnostic imaging x-ray devices

General Medical Italia LTD Swiss Branch
Via Roncaglia 2, 6883 Novazzano, Switzerland

Production



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