



CERTIFICATE OF REGISTRATION

This is to certify that

Gilardoni SpA

Via Arturo Gilardoni, Mandello Del Lario, Lecco 23826 Italy
D-U-N-S: 42-900-2678

operates a

Quality Management System

which complies with the requirements of

**ISO 13485:2016 and the requirements of the following
regulatory authorities**

Canada:

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

United States:

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

Design, production, trading and assistance of medical devices for imaging diagnostic and for ionizing radiations treatment.

Certificate No.: CERT-0130753
File No.: 1712694
Issue Date: 2020-07-17

Original Certification Date: 2020-07-16
Certification Effective Date: 2020-07-16
Certificate Expiry Date: 2023-07-15

Heather Mahon
Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP
authorized auditing organization.



Registered by:

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