



MDSAP CERTIFICATE
Certificate No. 014.22/MDSAP

This is to certify that

GILARDONI S.P.A.

Via Arturo Gilardoni 1, 23826 Mandello del Lario (LC), Italy

Facility ID: F006604

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

Canada:

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

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

Reference to IMQ files Nos.:

DM22-0085481-01; DM23-0087875-01

Original Certification Date:	2022-12-14
Issue Date:	2023-05-30
Certification Effective Date:	2023-07-16
Expiry Date:	2026-07-15

IMQ

Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization