CERTIFICATE OF REGISTRATION

This is to certify that

IMS GIOTTO S.p.A.

Via Sagittario, 5, Sasso Marconi, Bologna 40037 Italy

D-U-N-S: 437701793

operates a

Quality Management System

which complies with the requirements of

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

Australia:

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

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

The Design, manufacture, distribution, installation and service of active medical devices utilizing ionizing radiation and software for mammography systems and accessories including the transfer and management of digital images coming from diagnostic imaging equipment.

Certificate No.:	CERT-0136930	Original Certification Date:	2021-05-17
File No.:	1721479	Certification Effective Date:	2021-05-17
Issue Date:	2021-05-17	Certificate Expiry Date:	2024-05-16

Frank Camasta
Global Head of Technical Services
SAI Global Assurance

SAI Global is an MDSAP authorized auditing organization.

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certified System

ISO 13485:2016