



CERTIFICATE OF REGISTRATION

This is to certify that

STEELCO S.p.A.

Via Balegante, 27; Via Del Lavoro, 12; Via Del Lavoro, 3; Via Del Lavoro 9/A Riese Pio X, Treviso 31039 Italy

D-U-N-S: 428717469, 339685052, 439674241, 440379250

Refer to Attachment to Certificate of Registration dated January 21, 2021 for additional certified sites

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

Brazil:

- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009 - Vigilance

Canada:

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

Japan:

- MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
- Japan PMD Act (as applicable)

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, manufacture, installation and service of washer disinfectors, flusher disinfectors, decontamination cleaners, endoscope washers, steam sterilizers and low temperature sterilizers used in the management of medical devices and instruments disinfection and sterilization. Design and manufacture of disinfectant solutions for invasive and noninvasive medical devices.

Certificate No.: CERT-0128344

Original Certification Date: 2020-12-30

File No.: 1642149

Certification Effective Date: 2020-12-30

Issue Date: 2021-01-21

Certificate Expiry Date: 2023-12-29

Frank Camasta
Global Head of Technical Services
SAI Global Assurance



ISO 13485:2016

SAI Global is an authorized MDSAP auditing organization.



Registered by:
QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.
To verify that this certificate is current, please refer to the SAI Global On-Line Certification Register:
https://www.saiglobal.com/en-us/assurance/auditing_and_certification/certification_register/



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0128344 issued on January 21, 2021

File No.

Effective Date

1642149

STEELCO S.p.A.

2020-12-30

**Via Balegante, 27; Riese Pio X, Treviso 31039 Italy
D-U-N-S: 428717469**

Design, manufacture, installation and service of washer disinfectors, flusher disinfectors, decontamination cleaners, endoscope washers, steam sterilizers and low temperature sterilizers used in the management of medical devices and instruments disinfection and sterilization. Design and manufacture of disinfectant solutions for invasive and noninvasive medical devices.

**Via Del Lavoro, 12; Riese Pio X, Treviso 31039 Italy
D-U-N-S: 339685052**

Manufacturing (components).

**Via Del Lavoro, 3; Riese Pio X, Treviso 31039 Italy
D-U-N-S: 439674241**

Production and Service Controls (finished device), Assembly, Packaging/Labeling.

**Via Del Lavoro 9/A, Riese Pio X, Treviso 31039 Italy
D-U-N-S: 440379250**

Production and Service Controls (finished device), Manufacturing (components).