



MDSAP CERTIFICATE

Certificate No. 006.22-3/MDSAP

This is to certify that

STEELCO S.p.A.

Main site: Via Balegante 27, Riese Pio X, Treviso, 31039, Italy

Facility ID: F006592

Refer to Attachment to Certificate of Registration for additional certified sites

Operates a

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

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (as applicable)

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

United States:

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 - Subparts A to D
- 21 CFR Part 820

Canada:

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

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.

Reference to IMQ files Nos.:

DM22-0084116-01; DM23-0093730-01; DM24-0111473-01; DM24-0107086-01

Effective Date:

2025-01-29

Expiry Date:

2026-12-29

Issued on:

2025-01-29

IMQ

Matteo Raimondi – IMQ MDSAP Director



IMQ S.p.A. is an MDSAP Recognized Auditing Organization

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 006.22-3/MDSAP

Site address	Site scope
STEELCO S.p.A. Via Balegante 27 Riese Pio X, Treviso, 31039, Italy Facility ID: F006592	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.
STEELCO S.p.A. Via Del Lavoro 12 Riese Pio X, Treviso, 31039, Italy Facility ID: F006592	Manufacturing (components)
STEELCO S.p.A. Via Del Lavoro 3 Riese Pio X, Treviso, 31039, Italy Facility ID: F006592	Production and Service Controls (finished device), Assembly, Packaging/Labelling.
STEELCO S.p.A. Via Del Lavoro 9/A Riese Pio X, Treviso, 31039, Italy Facility ID: F006592	Production and Service Controls (finished device), Manufacturing (components)
STEELCO S.p.A. Via Del Lavoro 6-8 Riese Pio X, Treviso, 31039, Italy Facility ID: F006592	Storage of raw materials, components and finished devices
STEELCO S.p.A. Via Balegante, 5E-5F Riese Pio X, Treviso, 31039, Italy Facility ID: F006592	Acceptance, storage and shipment of finished products (consumables medical devices)