



MDSAP CERTIFICATE

Certificate No. 006.22-1/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 Device 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

Effective Date: 2023-12-30

Expiry Date: 2026-12-29

Issued on: 2023-12-19

IMQ

Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization

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This MDSAP certificate is subjected to the provisions laid down by IMQ in the "Regulation for Conformity Assessment Activities pursuant to Medical Device Single Audit Program (MDSAP) for which IMQ operates as Auditing Organization". The validity of this certificate can be verified by writing to MDSAP@imq.it.

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 006.22-1/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 |