



MDSAP CERTIFICATE

Certificate No. 006.22/MDSAP

This is to certify that

STEELCO S.p.A.

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

Facility ID: F005093

Refer to Attachment to Certificate of Registration dated November 10, 2022 for additional certified sites

Operates a

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

Brazil:

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

Canada:

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

Japan:

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

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, 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

Issue Date:	2022-11-10
Certification Effective date:	2022-11-10
Expiry Date:	2023-12-29

IMQ
Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP auditing organization



ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 006.22/MDSAP issued on 2022-11-10

Site address	Site scope	Effective Date
<p>STEELCO S.p.A. Via Balegante 27 Riese Pio X, Treviso, 31039, Italy MDSAP Facility Identifier: F005093</p>	<p>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.</p>	<p>2022-11-10</p>
<p>STEELCO S.p.A. Via Del Lavoro 12 Riese Pio X, Treviso, 31039, Italy MDSAP Facility Identifier: F005093</p>	<p>Manufacturing (components).</p>	<p>2022-11-10</p>
<p>STEELCO S.p.A. Via Del Lavoro 3 Riese Pio X, Treviso, 31039, Italy MDSAP Facility Identifier: F005093</p>	<p>Production and Service Controls (finished device), Assembly, Packaging/Labelling.</p>	<p>2022-11-10</p>
<p>STEELCO S.p.A. Via Del Lavoro 9/A Riese Pio X, Treviso, 31039, Italy MDSAP Facility Identifier: F005093</p>	<p>Production and Service Controls (finished device), Manufacturing (components).</p>	<p>2022-11-10</p>
<p>STEELCO S.p.A. Via Del Lavoro 6-8 Riese Pio X, Treviso, 31039, Italy MDSAP Facility Identifier: F005093</p>	<p>Storage of raw materials, components and finished devices.</p>	<p>2022-11-10</p>