



CERTIFICATE OF REGISTRATION

This is to certify that

W&H Sterilization S.r.l.

Main Site: Via Bolgara 2 Associated Site 1: Via Maestri del Lavoro 20 Brusaporto, Bergamo 24060 Italy

D-U-N-S: 429111904

Refer to Attachment to Certificate of Registration dated July 13, 2020 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

The registration covers the Quality Management System for design, manufacture, service and distribution of small steam sterilizers and related optional.

Certificate No.: CERT-0125660

File No.: 026252

Issue Date: 2020-07-13

Original Certification Date: 2019-12-12

Certification Effective Date: 2019-12-12

Certificate Expiry Date: 2022-12-11

Heather Mahon

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-0125660 issued on July 13, 2020

File No.		Effective Date
026252	W&H Sterilization S.r.l. Main Site: Via Bolgara 2 Associated Site 1: Via Maestri del Lavoro 20 Brusaporto, Bergamo 24060 Italy D-U-N-S: 429111904 Design, manufacture, service and distribution of small steam sterilizers and related optional.	2019-12-12
026252	W&H Sterilization S.r.l. Via Maestri del Lavoro, 20, Brusaporto (BG), Bergamo, Italy D-U-N-S: 440501501 The manufacture and assembly of small steam sterilizers.	2020-07-11