



## MDSAP CERTIFICATE

### Certificate No. 001.22/MDSAP

This is to certify that

### **W&H Sterilization S.r.l.**

Main site: Via Bolgara 2, Brusaporto, Bergamo, 24060, Italy

**Facility ID: F004366**

**Refer to Attachment to Certificate of Registration dated February 06, 2023 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

**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, service and distribution of steam sterilizing units and related optional.**

Reference to IMQ files Nos.:

DM22-0083411-01; DM22-0083419-01; DM23-0086947-01

Original Certification Date:	2022-10-24
Issue Date:	2023-02-06
Certification Effective Date:	2022-12-06
Expiry Date:	2025-12-05

---

**IMQ**

**Eng. Fulvio Giorgi – IMQ MDSAP Director**

IMQ is an authorized MDSAP Auditing Organization



## ATTACHMENT TO CERTIFICATE OF REGISTRATION

**These sites are registered under Certificate No. 001.22/MDSAP issued on 2023-01-27**

<b>Site address</b>	<b>Site scope</b>	<b>Effective Date</b>
W&H Sterilization S.r.l. Via Bolgara 2 Brusaporto, Bergamo, 24060, Italy <b>MDSAP Facility Identifier:</b> F004366	Design, manufacture, servicing and distribution of small steam sterilizers and related optional.	2022-10-24
W&H Sterilization S.r.l. Via Maestri del Lavoro 20 Brusaporto, Bergamo, 24060, Italy <b>MDSAP Facility Identifier:</b> F004366	Manufacture and assembly of small steam sterilizers.	2022-10-24