



CERTIFICATE OF REGISTRATION

This is to certify that

OMNIA SRL

Via Francesco Delnevo, 190, Fidenza, Parma 43036 Italy

D-U-N-S: 44-769-6675

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

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

Manufacture and distribution of reusable dental instruments for use in dental surgical procedures. Manufacture and distribution of medical devices sterile and non-sterile for the prevention of cross contamination. Manufacture and distribution of sterile medical devices such as custom surgical packs, irrigation lines, aspiration tips, soft tissue punches and surgical non-absorbable sutures for use in dental surgical procedures. Manufacture and distribution of lithotripsy probes. Design, manufacture and distribution of micro pins and micro screws for use in maxillofacial and dental surgery.

Certificate No.: CERT-0126046

Original Certification Date: 2020-07-28

File No.: 1629020

Certification Effective Date: 2020-07-28

Issue Date: 2020-08-05

Certificate Expiry Date: 2023-07-27

Heather Mahon

Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP
authorized 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_registry/

