# 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.**

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Heather Mahon
Global Head of Technical Services SAI Global Assurance

ISO 13485:2016

SAI Global is an MDSAP authorized auditing organization.

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM



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