



CERTIFICATE OF REGISTRATION

This is to certify that

Rhein 83 SRL

Via Emilio Zago, 10/ABC, Bologna 40128 Italy

D-U-N-S: 43-924-0722

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

Design, manufacturing and technical assistance of attachments, instruments, components for dental prostheses.

Certificate No.: CERT-0127452

File No.: 1067163

Issue Date: 2020-10-19

Original Certification Date: 2020-10-16

Certification Effective Date: 2020-10-16

Certificate Expiry Date: 2023-10-15

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/

