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	Original Certification Date:	2020-10-16
File No.:	1067163	Certification Effective Date:	2020-10-16
Issue Date:	2020-10-19	Certificate Expiry Date:	2023-10-15

Heather Mahon
Global Head of Technical Services SAI Global Assurance

Certified System ™
ISO 13485:2016

SAI Global is an MDSAP authorized auditing organization.
MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

SAI GLOBAL INFORM. INSPIRE. IMPROVE.