

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.: File No.: Issue Date:

CERT-0127452 1067163 2020-10-19

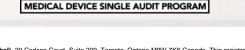
Original Certification Date: 2020-10-16 Certification Effective Date: 2020-10-16 Certificate Expiry Date: 2023-10-15

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Heather Mahon **Global Head of Technical Services** SAI Global Assurance







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