

MDSAP CERTIFICATE

Certificate No. 018.22-1/MDSAP

This is to certify that **Rhein 83 S.R.L.** Via Emilio Zago 10/ABC, 40128 Bologna, Italy **Facility ID: F006609**

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

Australia:

• Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

• Medical Device Regulations – Part 1 - SOR/98-282

for the following scope of certification

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68
PMD Act (as applicable)

United States:

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 Subparts A to D
- 21 CFR Part 820

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

Reference to IMQ files Nos.: DM22-0085925-01; DM23-0090343-01

 Effective Date:
 2023-10-16

 Expiry Date:
 2026-10-15

 Issued on:
 2023-09-04

 Fulvio Giorgi – IMQ MDSAP Director

 IMQ is an authorized MDSAP Auditing Organization

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This MDSAP certificate is subjected to the provisions laid down by IMQ in the "Regulation for Conformity Assessment Activities pursuant to Medical Device Single Audit Program (MDSAP) for which IMQ operates as Auditing Organization". The validity of this certificate can be verified by writing to MDSAP@imq.it.