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

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

for the following scope of certification

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

IMQ

Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization