



## MDSAP CERTIFICATE

### Certificate No. 018.22-2/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 Devices 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; DM24-0111435-01

Effective Date: 2024-11-11

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**IMQ**

**Matteo Raimondi – IMQ MDSAP Director**



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