



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7279GB451230216

Final assessment report no.
7279AU08F

Effective date
2023-02-16

Expiry date
2024-03-18

This is to certify that the management system of

S&S Scheftner GmbH

Dekan-Laist-Straße 52, 55129 Mainz, Germany

Facility ID: F006033

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard

ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2023-02-16

DNV MEDCERT is an MDSAP
authorised auditing organisation

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

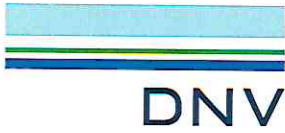
The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de

Markus Bianchi
Director Certification Body

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820114 EN Rev 5 2022.11.16

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
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Certificate no.: 7279GB451230216
Place and date: Hamburg, 2023-02-16

Activities and products/services covered by this certificate

Design and development, manufacture, and distribution of

- Dental materials
 - Non- precious alloys
 - Titanium, titanium alloys
 - Non-precious solders

Sites covered by this certificate

S&S Scheftner GmbH, Dekan-Laist-Straße 52, 55129 Mainz, Germany
Facility ID: F006033

Site-specific scope

Design and development, manufacture, and distribution of

- Dental materials
 - Non- precious alloys
 - Titanium, titanium alloys
 - Non-precious solders