



MDSAP CONFORMITY CERTIFICATE

Certificate No. NCC 23.10044

Revision nº: 00

Date of Issue: 25/05/2023

Expiration date: 25/05/2026

NCC Certificações do Brasil Ltda., an MDSAP authorized Auditing Organization, certifies that the Quality Management System of:

SIN - Sistema de Implante Nacional S.A.

Data of the Organization:

Address: Soldado Ocimar Guimarães da Silva Street, nº 421, Vila Regente Feijó / Vereador Abel Ferreira Avenue, nº 2140 - Brasil, **Zip Code: 03340-000, CNPJ:** 04.298.106/0001-74

Facility's identification number - (REPs): F006773

has been found to conform to the Quality Management System Standard

ISO 13485:2016

Brasil: RDC ANVISA nº 665/2022; RDC ANVISA nº 551/2021; RDC ANVISA nº67/2009

Canadá: Medical Devices Regulations – Part 1- SOR 98/282

EUA : 21 CFR 820.20

Scope: "Design, manufacture and distribution of sterile dental implants, sterile and non-sterile prosthetic components and non-sterile surgical instruments"

Not applicable items:

- 7.5.3: Installation activities;
- 7.5.4: Servicing activities;
- 7.5.10: Customer property.

It's possible to find the information of the validity of this certificate in NCC's web site: <http://www.nccgroup.com.br>

Wilson Bonato

Gerente Técnico / Technical Manager

Certification History

Revision	Certificate	Date of issue	Process	Description
00	NCC 23.10044	25/05/2023	77552/22.1	Emission Initial

NCC Certificações do Brasil Ltda.
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