



MDSAP CONFORMITY CERTIFICATE

Certificate No. NCC 23.10044.03

Effective Date: 2023/05/25

Expiry Date: 2026/05/25

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

S.I.N - Implant System LTDA.

Data of the Organization:

Address: Front Gate - Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco - São Paulo/SP
CEP: 03.348-060 / Back Gate - Avenida Vereador Abel Ferreira, 2140 - Vila Regente Feijó - São Paulo/SP
CEP: 03.340-000, 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

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3, Part 1 (excluding Part 1.6) - Full Quality Assurance System

Brazil:

RDC ANVISA nº 665/2022, RDC ANVISA nº 551/2021, RDC ANVISA nº 67/2009

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

Japan:

MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
Japan PMD Act (as applicable)

USA:

21 CFR Part 803 - Medical Device Reporting / 21 CFR Part 806 - Reports of Corrections and Removals
21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
21 CFR Part 820 - Quality System Regulation / 21 CFR Part 821 - Device Tracking

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*.

Further clarifications regarding this certificate, such as: revision, expiry date, scope description, standards and status, may be obtained by consulting the NCC/BV site <https://www.nccgroup.com.br/atuacao/mdsap/certificados-emitidos-mdsap/>.

Further clarifications regarding the scope of this certificate and the applicability of MDSAP Requirements may be obtained by Consulting the Organization.



Assinado de forma digital por
WILSON MONTEIRO BONATO
JUNIOR:04261009803

Wilson Bonato
Technical Manager

Certification History

Revision	Certificate	Date of issue	Process	Description
00	NCC 23.10044	2023/05/25	77552/22.1	Initial Emission
01	NCC 23.10044	2024/01/09	77552/22.1.Rev1	Inclusion of jurisdictions (Australia and Japan)
02	NCC 23.10044	2024/04/30	77552/22.1.Rev1.M1	Update the company name and address
03	NCC 23.10044	2024/09/13	77552/22.1.M1.Rev2	Certificate template update

NCC Certificações do Brasil Ltda.
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CNPJ nº 16.587.151/0001-28
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Página 1 de 1