EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until
286024-2019-CE-BRA-NA-PS Ver 2.0	PRJC-535717-2015-MSL-BRA	27 May 2024

This is to certify that the quality system of:

SIN SISTEMA DE IMPLANTE NACIONAL S/A

Front Gate - Avenida Vereador Abel Ferreira 1100, São Paulo, SP, 03340-000, Brazil. Back Gate - Rua Soldado Ocimar Guimarães da Silva 2445, São Paulo, SP, 03348-060, Brazil.

For design, production and final product inspection/testing of:

DENTAL SURGICAL INSTRUMENTS

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 29 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	04-06-2019
1.0	Format change of certificate template. Change of European Representative.	15-05-2020
2.0	**Format change of certificate template.** **Scope Extension.**	**29-03-2021**

Products covered by this Certificate:

Product Description	Product Name	Class
DENTAL SURGICAL INSTRUMENTS	**DRILLS** EXTRACTING / COUNTERSINK / HELICAL CONIC / LANCE / PILOT / TREPHINE BONE PROFILE / SPHERICAL / SCREW TAP **DRIVERS** **KITS:** KCHE 04 / KCSW 02 / KCSU 03 / KCSE 01 KZ / KCSWG 02 / KCSWG 04 / KCSUG 02 KCSUG 04 / KSDSW / KSDU / KRFT / KRFTC KRFU / KRFSW / KENX / KER / KOR	IIa

The complete list of devices is filed with the Notified Body:
List of Devices_Surgical Instruments_Non Sterile_IIa_Rev.01

Sites covered by this certificate

Site Name	Address
SIN SISTEMA DE IMPLANTE NACIONAL S/A	Front Gate - Avenida Vereador Abel Ferreira 1100, São Paulo, SP, 03340-000, Brazil.

	Back Gate - Rua Soldado Ocimar Guimarães da Silva 2445, São Paulo, SP, 03348-060, Brazil.

EU Representative

OBELIS S.A. Bd. Général Wahis 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

APPENDIX TO EC CERTIFICATE

Certificate no.:
286024-2019-CE-BRA-NA-PS Ver 2.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
SIN - SISTEMA DE IMPLANTE NACIONAL S.A.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Review of the complete list of devices with the Notified Body.

The complete list of devices is filed with the Notified Body:
List of Devices Surgical Instruments_Non Sterile_IIa_Rev.02

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Update of the approved list of certified devices	16 February 2024

Place and date:
Høvik, 16 February 2024

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

APPENDIX TO EC CERTIFICATE

Certificate no.:
286024-2019-CE-BRA-NA-PS Ver 2.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
S.I.N. Implant System LTDA

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Sites covered by certificate (replaces information on certificate)	
Site Name	**Site Address**
S.I.N. Implant System LTDA	**Front Gate** - Rua Soldado Ocimar Guimarães da Silva **421**, Vila Rio Branco, 03348-060, São Paulo, SP, Brazil. **Back Gate** - Avenida Vereador Abel Ferreira **2140**, Jd. Analia Franco, 03340-000, São Paulo, SP, Brazil.

Place and date:
Høvik, 22 May 2024

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Update of the approved list of certified devices	16 February 2024
1.0	Company legal name change: **S.I.N. Implant System LTDA**. Administrative address change: **Front Gate** - Rua Soldado Ocimar Guimarães da Silva **421**, Vila Rio Branco, 03348-060, São Paulo, SP, Brazil. **Back Gate** - Avenida Vereador Abel Ferreira **2140**, Jd. Analia Franco, 03340-000, São Paulo, SP, Brazil.	22 May 2024

Notified Body Confirmation Letter Reference: C662286

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

S.I.N. IMPLANT SYSTEM LTDA

Front Gate - Rua Soldado Ocimar Guimarães da Silva 421,
Vila Rio Branco, São Paulo, SP, 03348-060, Brazil.

Back Gate - Avenida Vereador Abel Ferreira 2140,
Jd. Analia Franco, São Paulo, SP, 03340-000, Brazil.

SRN Number (if available): BR-MF-000019848

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 29.05.2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dental Implant System - External Hexagon Basic UDI-DI: 999520000040JS	Class IIb	NON-STERILE PROSTHETIC COMPONENTS (Only Name Change) STERILE DENTAL IMPLANTS (Only Name Change) STERILE PROSTHETIC COMPONENTS (Only Name Change)	Certificate Number: 216892-2017-CE-BRA-NA-PS Rev 4.0 Appendix to EC Certificate Rev 1.0 - 216892-2017-CE-BRA-NA-PS Rev 4.0 NB Name: DNV Product Assurance AS NB number: 2460
Dental Implant System - Internal Hexagon Basic UDI-DI: 999520000041JU	Class IIb	NON-STERILE PROSTHETIC COMPONENTS (Only Name Change) STERILE DENTAL IMPLANTS (Only Name Change) STERILE PROSTHETIC COMPONENTS (Only Name Change)	Certificate Number: 216892-2017-CE-BRA-NA-PS Rev 4.0 Appendix to EC Certificate Rev 1.0 - 216892-2017-CE-BRA-NA-PS Rev 4.0 NB Name: DNV Product Assurance AS NB number: 2460
Dental Implant	Class IIb	NON-STERILE	Certificate Number:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
System – Cone Morse Basic UDI-DI: 999520000042JW		PROSTHETIC COMPONENTS (Only Name Change) STERILE DENTAL IMPLANTS (Only Name Change) STERILE PROSTHETIC COMPONENTS (Only Name Change)	216892-2017-CE-BRA-NA-PS Rev 4.0 Appendix to EC Certificate Rev 1.0 - 216892-2017-CE-BRA-NA-PS Rev 4.0 NB Name: DNV Product Assurance AS NB number: 2460
Drill and Driver Basic UDI-DI: 999520000043JY	Class IIa	DENTAL SURGICAL INSTRUMENTS (Only Name Change)	Certificate Number: 286024-2019-CE-BRA-NA-PS Rev 2.0 Appendix to EC Certificate Rev 1.0 - 286024-2019-CE-BRA-NA-PS Rev 2.0 NB Name: DNV Product Assurance AS NB number: 2460

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Reusable Surgical Instruments Basic UDI-DI: 999520000044K2	Class Ir	N.A.	DoC: Surgical Instruments (rev09)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/29	C662286	Initial issue
2024/05/28	C662286	Updated the legal name Added CE Certificate Appendixs Updated DoC version of “Reusable Surgical Instruments”
2024/05/29	C662286	Updated the legal manufacturer address

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.