EC CERTIFICATE
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until
216892-2017-CE-BRA-NA-PS Rev 4.0	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 IMPLANTS AND PROSTHETIC COMPONENTS

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, 23 April 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	Replaces certificate 199842-2016-CE-BRA-NA following transfer of Notified Body functions to DNV GL Nemko Presafe AS.	27 Sep 2017
1.0	Scope extension and address correction.	18 Sep 2019
2.0	Format change of certificate template. Voluntary scope reduction. Change of European Representative.	13 May 2020
3.0	Format change of certificate template. Recertification with Scope Extension.	29 March 2021
4.0	**Certificate number correction**	**23 April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
STERILE DENTAL IMPLANTS	[TRYON LINE] Implant Tryon CM Cylindrical Implant Tryon CM Conical Implant Tryon HE Cylindrical Implant Tryon HE Conical [STRONG SW LINE] Implant Strong SW Implant Strong SW CM Implant Strong SW HE Implant Strong SW HI Implant Strong SW Plus Implant Strong SW CM Plus Implant Strong SW HE Plus Implant Strong SW HI Plus [UNITITE LINE] Implant Unitite Implant Unitite Compact Implant Unitite Slim	IIb

STERILE DENTAL IMPLANTS	[ZYGOMATIC LINE] Implant Zygomatic [EPIKUT LINE] Implant Epikut CM Implant Epikut HE Implant Epikut Plus CM Implant Epikut Plus HE	IIb
STERILE PROSTHETIC COMPONENTS	Mini-abutment Angled Mini-abutment Conical Abutment Cemented Abutment Angled Cemented Abutment Interface Abutment Accessories: Screws	IIb
STERILE PROSTHETIC COMPONENTS	Healing Caps Protectors	IIa
NON-STERILE PROSTHETIC COMPONENTS	Temporary Abutments Metallic Abutments	IIa

The complete list of devices is filed with the Notified Body:
List of Devices_Dental Implants_Sterile_IIb_Rev.06
List of Devices_Prosthetics Components_Non Sterile_IIb_Rev.04
List of Devices_Prosthetics Components_Sterile_IIa_Rev.05
List of Devices_Prosthetics Components_Sterile_IIb_Rev.05

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