DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
216892-2017-CE-BRA-NA-PS Rev 2.0	PRJC-535717-2015-MSL-BRA	27 July 2021

This is to certify that the quality system of:

SIN SISTEMA DE IMPLANTE NACIONAL

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, 13 May 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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**

Products covered by this Certificate:

Product Description	Product Name	Class
Dental Implants (Sterile)	Internal Hexagon, External Hexagon and Morse Tapper Connection	IIb
Prosthetic Components (Sterile)	Abutments, Mini-Abutments, Angled Abutments, Angled Mini Abutments, Conical Abutments, Cemented Abutment, Angled Cemented Abutments, Overdenture System, Interfaces Abutments Accessories: Screws	IIb
Prosthetic Components (Sterile)	Healing Caps and Protectors	IIa
Prosthetic Components (Non Sterile)	Temporary Abutments and Metallic Abutments	IIb

The complete list of devices is filed with the Notified Body:

- List of Products Prosthetics Components Sterile IIb Rev.04
- List of Products Prosthetics Components Sterile IIa Rev.04
- **List of Products Dental Implants Sterile IIb Rev.05**
- List of Products Prosthetics Components Non-Sterile IIb Rev.03

Certificate No.:
216892-2017-CE-BRA-NA-PS Rev02

Project No.:
PRJC-535717-2015-MSL-BRA

Valid Until:
27 July 2021

Sites covered by this certificate

Site Name	Address
SIN SISTEMA DE IMPLANTE NACIONAL	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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate