

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
286024-2019-CE-BRA-NA-PS Rev. 1.0

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

Valid Until:  
27 May 2024

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 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, 15 May 2020**



For:  
**DNV GL PRESAFE AS**  
**Notified Body No.: 2460**

**Tone Elise Kolpus**

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



Certificate No.:  
286024-2019-CE-BRA-NA-PS Rev. 1.0

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

Valid Until:  
27 May 2024

### 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
<b>1.0</b>	<b>Format change of certificate template. Change of European Representative.</b>	<b>15-05-2020</b>

Products covered by this Certificate:

Product Description	Product Name	Class
Dental surgical instruments	DRILLS DRIVERS Kits: KCHE 02 / KCHE 03 / KCSU 02 / KCSU 03 / KCSUG 02 / KCSUG 04 / KCSW 02 / KCSWG 02 / KCSWG 04 / KENX / KER / KITOTN / KOR / KRC/ KRFSW / KRFT / KRFTC / KRFU/ KSDSW / KSDU / KZ	IIa

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

### 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**

Certificate No.:  
286024-2019-CE-BRA-NA-PS Rev. 1.0

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

Valid Until:  
27 May 2024

## 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