

EC Certificate

Full Quality Assurance System

Certificate No.:
286640-2019-CE-ARG-NA-PS

Project No.:
PRJC-341167-2011-MSL-ARG

Valid Until:
27 May 2024

This is to certify that the quality system of:

STEELDEC S.A.

VALPARAISO 4100 Parque Ind. Tortuguitas, (1667), Buenos Aires,
Argentina.

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

SYSTEMS OF DENTAL IMPLANTS (DENTAL IMPLANTS AND ABUTMENTS)

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, 17 July 2019



For:
DNV GL PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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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	17 July 2019

Products covered by this Certificate:

Product Description	Product Name	Class
<p>SYSTEMS OF DENTAL IMPLANTS (DENTAL IMPLANTS and ABUTMENTS)</p> <p><u>Brand name:</u> ML IMPLANT SYSTEM OSTEOPLUS NOVEL-TI</p>	<p><u>SHI CORTICAL IMPLANT SYSTEM:</u></p> <p>IMPLANT:</p> <ul style="list-style-type: none"> - SHI Cortical Internal Connection Implant <p>ABUTMENTS OF THE SYSTEM:</p> <ul style="list-style-type: none"> - Angulated abutment - Healing abutment - Mini abutment (Straight and angulated) - Straight Titanium abutment - Spherical Abutment (o´ring and equator) - Impression copping (open and closed) - Fixture mount - Ti-Base - Scan Body - Temporary - Screw <p><u>SRI IMPLANT SYSTEM:</u></p> <p>IMPLANT:</p> <ul style="list-style-type: none"> - SRI Internal Connection tri-channel Implant <p>ABUTMENTS OF THE SYSTEM:</p> <ul style="list-style-type: none"> - Angulated abutment - Healing abutment - Mini abutment (Straight and angulated) 	<p>IIb</p>

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	<ul style="list-style-type: none"> - Straight Titanium abutment - Spherical Abutment (o´ring and equator) - Impression copping (open and closed) - Fixture mount - Ti-Base - Scan Body - Temporary - Screw <p><u>SHE IMPLANT SYSTEM:</u></p> <p>IMPLANT:</p> <ul style="list-style-type: none"> - SHE External Connection Implant <p>ABUTMENTS OF THE SYSTEM:</p> <ul style="list-style-type: none"> - Anatomical titanium abutment - Rotational abutment - Titanium abutment with double screw - Angulated abutment - Healing abutment - Mini abutment (Straight and angulated) - Straight Titanium abutment - Spherical Abutment (o´ring and equator) - Impression copping (open and closed) - Fixture mount - Ti-Base - Scan Body - Temporary - Screw <p><u>SHI IMPLANT SYSTEM:</u></p> <p>IMPLANT:</p> <ul style="list-style-type: none"> - SHI Internal Connection Implant <p>ABUTMENTS OF THE SYSTEM:</p> <ul style="list-style-type: none"> - Angulated abutment - Healing abutment - Mini abutment (Straight and angulated) - Straight Titanium abutment - Spherical Abutment (o´ring and equator) - Impression copping (open and closed) - Fixture mount - Ti-Base - Scan Body - Temporary - Screw 	
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The complete list of devices is filed with the Notified Body:

Annex Complete list of dental implant system March-2019.

Sites covered by this certificate

Site Name	Address
STEELDEC S.A.	VALPARAISO 4100 Parque Ind. Tortuguitas, (1667), Buenos Aires, Argentina

EU Representative

IMPORTACIÓN DENTAL ESPECIALIDADES S.L

Av. De las Nieves 8, P.I. Las Nieves

Post Code: 28935, Móstoles, Madrid, Spain

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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