

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
10000336183-PA-NA-BRA

Project No.:  
PRJC-525596-2015-MSL-BRA

Valid Until:  
25 May 2024

This is to certify that the quality system of:

### RIELLEN'S INDUSTRIA E COMERCIO LTDA EPP

RUA FERNANDO DE NORONHA, 785, 06.730-000, VARGEM GRANDE PAULISTA,  
BRAZIL.

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

### NON-STERILE COMPONENTS FOR DENTAL IMPLANTS

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, 06 January 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)



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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	2020-01-06

Products covered by this Certificate:

Product Description	Product Name	Class
TEMPORARY ABUTMENT	PRNPA-B TEMPORARY ABUTMENT NP A.R HE B PRRPA-B TEMPORARY ABUTMENT RP A.R HE B PRWPA-B TEMPORARY ABUTMENT WP A.R HE B PRNPR-B TEMPORARY ABUTMENT NP ROT. HE B PRRPR-B TEMPORARY ABUTMENT RP ROT. HE B PRWPR-B TEMPORARY ABUTMENT WP ROT. HE B PRRPR-MU TEMPORARY ABUTMENT RP ROT. M.U PRWPR-MU TEMPORARY ABUTMENT WP ROT. M.U	I Ib
PROSTHETIC SCREW	HE B MU	I Ib
HEALING	HE B MU	I Ib
UCLA COBAL CHROME BASE	HE B MU	I Ib

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

Site Name	Address
RIELLEN'S INDUSTRIA E COMERCIO LTDA EPP	RUA FERNANDO DE NORONHA, 785, 06.730-000, VARGEM GRANDE PAULISTA, BRAZIL.

**EU Representative**

EXAKTUS-MATERIAL DE REABILITAÇÃO ORAL LDA.  
Rua de Laborín, 68, Vila Nova Gaia, 4400-125 – Portugal  
Phone: 351 915672196

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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