EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
260501-2018-CE-BRA-NA-PS	**PRJC-384469-2012-MSL-BRA**	**13 August 2023**

This is to certify that the quality system of:

BIONNOVATION PRODUTOS BIOMÉDICOS LTDA

Rua Laureano Garcia 1-275. Distrito Industrial II. 17039-760. Bauru - SP- Brazil.

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

DENTAL METAL IMPLANTS AND ACCESSORIES

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) 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 August 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Cathrine Wisbech
Management Representative

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.

EC Certificate
Full Quality Assurance System

Certificate No.: **260501-2018-CE-BRA-NA-PS**
Project No.: **PRJC-384469-2012-MSL-BRA**
Valid Until: **13 August 2023**

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
	Original Certificate	2018-08-13

Products covered by this Certificate:

Product Description	Product Name	Class
Implant System (Sterile)	Conic Implant E.H Conic Implant E.H Non-Mount Conic Implant Biodirect Conic Implant I.H Conic Implant I.H Non-Mount CLASSIC Implant E.H CLASSIC Implant E.H Non-Mount CLASSIC Implant Biodirect CLASSIC Implant I.H CLASSIC Implant I.H Non-Mount Conic Implant Medular I.H Classic Implant Medular I.H Conic Implant Biomorse Classic Implant Biomorse Mount for Implants E.H Mount for Implants I.H Cover screw E.H Cover screw I.H	IIb
Prosthetic Components (Sterile)	Healing Abutment (Sterile): Healing Abutment HE Healing Abutment HI Healing Abutment CM Tiprep Abutment (Sterile): Tiprep Abutment HE Angled Tiprep Abutment HE Straight Tiprep Abutment HI Angled Tiprep Abutment HI Straight Tiprep Abutment CM Angled	IIb

EC Certificate
Full Quality Assurance System

Certificate No.: **260501-2018-CE-BRA-NA-PS**
Project No.: **PRJC-384469-2012-MSL-BRA**
Valid Until: **13 August 2023**

Product Description	Product Name	Class
	Tiprep Abutment CM Straight Mini Conical Abutment (Sterile): Mini Conical Abutment HE Mini Conical Abutment HE Angled Mini Conical Abutment HI Mini Conical Abutment HI Angled Mini Conical Abutment CM Conical Abutment (Sterile): Conical Abutment HE Conical Abutment HE Angled Conical Abutment HI Conical Abutment HI Angled Universal Abutment CM (Sterile) Spherical Abutment (Sterile): Spherical Abutment HE Abutment Screw (Sterile): Abutment Screw HE Abutment Screw HE DLC Abutment Screw HI Abutment Screw HI DLC Abutment Screw CM Abutment Screw CM DLC Mini Conical Abutment Screw (Sterile): Mini Conical Abutment Screw HE Mini Conical Abutment Screw HE Angled Mini Conical Abutment Screw HI Mini Conical Abutment Screw HI Angled	
Prosthetic Components (Non-Sterile)	Titanium Abutment (Non-Sterile): Titanium Abutment HE Titanium Abutment HE DLC Titanium Abutment CM Titanium Abutment Universal CM Titanium Abutment Mini Conical CM Healing Cap (Non-Sterile): Conical Abutment Healing Cap Mini Conical Abutment Healing Cap Mini Conical Abutment Healing Cap Angled Mini Conical Abutment Healing Cap CM Spherical Abutment Components (Non-Sterile): O'ring Cylinder for replacement for Spherical Abutment Metallic Cylinder and Ring for Spherical Abutment Plastic Cylinder and O'rings	IIb

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
260501-2018-CE-BRA-NA-PS	**PRJC-384469-2012-MSL-BRA**	**13 August 2023**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
BIONNOVATION PRODUTOS BIOMÉDICOS LTDA	Rua Laureano Garcia 1-275. Distrito Industrial II. 17039-760. Bauru - SP- Brazil.

EU Representative

Bionnovation Europe S.L

NIF B66633330

Calle Enmedio, 20 1a Planta 28850 Torrejón de Ardoz, Madrid, Spain

Phone +34 615371648

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
260501-2018-CE-BRA-NA-PS	**PRJC-384469-2012-MSL-BRA**	**13 August 2023**

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