



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 120403-2012-CE-BRA-NA 1.0

This Certificate consists of 2 pages

This is to certify that the Quality Management System of

BIONNOVATION PRODUTOS BIOMÉDICOS LTDA

RUA JOSÉ MARIA LISBOA 860-SALAS123 E 124. JARDIM PAULISTA.01423-001. SÃO PAULO - SP. BRAZIL.
RUA LAUREANO GARCIA 1-275. DISTRITO INDUSTRIAL II. 17039-760. BAURU - SP- BRAZIL.

for design, production and final product inspection/testing of

Dental 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 H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 08 February 2013

This Certificate is valid until:

07 October 2017

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY



Aud Løken Eiklid
Certification Manager

Notified Body No.:
0434

Mariann Jeremiassen
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0	Transfer from another NB (Take over).	
1	Recertification	2012-10-07

Product Description	Product	Class
Implant System (Sterile)	Implant Conic HE Implant Conic HE without mount Implant Conic HE direct torque Implant Conic HI Implant Conic HI without mount Implant Cylindric CLASSIC HE Implant Cylindric CLASSIC HE without mount Implant Cylindric CLASSIC HE direct torque Implant Cylindric CLASSIC HI Implant Cylindric CLASSIC HI without mount Implant Medullar Conic HI Implant Medullar Cylindric HI Implant Cone Morse Conic Implant Cone Morse Cylindric Mount for Implants HE Mount for Implants HI Cover screw HE Cover screw HI	IIb
Prosthetic Components (Sterile and Non-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	IIa



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<p>Tiprep Abutment CM Straight</p> <p>Mini Conical Abutment (Sterile)</p> <p>Mini Conical Abutment HE</p> <p>Mini Conical Abutment HE Angled</p> <p>Mini Conical Abutment HI</p> <p>Mini Conical Abutment HI Angled</p> <p>Mini Conical Abutment CM</p> <p>Conical Abutment (Sterile)</p> <p>Conical Abutment HE</p> <p>Conical Abutment HE Angled</p> <p>Conical Abutment HI</p> <p>Conical Abutment HI Angled</p> <p>Universal Abutment CM (Sterile)</p> <p>Spherical Abutment (Sterile)</p> <p>Spherical Abutment HE</p> <p>Abutment Screw (Sterile)</p> <p>Abutment Screw HE</p> <p>Abutment Screw HE DLC</p> <p>Abutment Screw HI</p> <p>Abutment Screw HI DLC</p> <p>Abutment Screw CM</p> <p>Abutment Screw CM DLC</p> <p>Mini Conical Abutment Screw (Sterile)</p> <p>Mini Conical Abutment Screw HE</p> <p>Mini Conical Abutment Screw HE Angled</p> <p>Mini Conical Abutment Screw HI</p> <p>Mini Conical Abutment Screw HI Angled</p> <p>Ucla Abutment (Non-Sterile)</p> <p>Ucla Abutment HE Plastic</p>	
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Ucla Abutment HI Plastic
Ucla Abutment HE Injected
Ucla Abutment HI Injected
Ucla Abutment HE CoCr
Ucla Abutment HI CoCr
Ucla Abutment CM CoCr

Impression Coping (Non-Sterile)

Impression Coping HE
Impression Coping HI
Impression Coping CM
Impression Coping Conical Abutment
Impression Coping Mini Conical Abutment
Impression Coping Mini Conical Abutment Angled
Impression Coping Mini Conical Abutment CM
Impression Coping Universal CM

Temporary Cylinder (Non-Sterile)

Temporary Cylinder HE
Temporary Cylinder HI
Temporary Cylinder Conical Abutment
Temporary Cylinder Mini Conical Abutment
Temporary Cylinder Mini Conical Abutment CM
Temporary Cylinder CM
Temporary Cylinder Universal CM

Titanium Abutment (Non-Sterile)

Titanium Abutment HE
Titanium Abutment HE DLC
Titanium Abutment CM
Titanium Abutment Universal CM
Titanium Abutment Mini Conical CM

Castable Copings (Non-Sterile)

Castable Coping Single Abutment HE Plastic
Castable Coping Conical Abutment Plastic
Castable Coping Mini Conical Abutment Plastic
Castable Coping Mini Conical Abutment CM



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	Castable Coping Universal Abutment 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 Prosthetic Screw (Sterile) Conical Abutment Prosthetic Screw Mini Conical Abutment Prosthetic Screw Prosthetic Screw CM	
Orthodontic Implant Mini (Sterile)	Orthodontic Implant Mini Ball Orthodontic Implant Mini Bracket	I Ib
PTFE Membrane (Sterile)	Surgitime PTFE	I Ib
Titanium Membrane (Scope Extension) (Sterile)	Surgitime Titanium	I Ib
Graft and Fixation Screw (Scope Extension) (Sterile)	Graft and Fixation Screw	I Ib

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

Sites covered by this certificate

BIONNOVATION PRODUTOS BIOMÉDICOS SA	RUA JOSÉ MARIA LISBOA 860-SALAS123 E 124. JARDIM PAULISTA. 01423-001. SÃO PAULO - SP. BRAZIL
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EU Representative



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BIONNOVATION EUROPE AB - Welandergatan 24, 41656 Goteborg

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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE