DET NORSKE VERITAS

PRODUCTION QUALITY MANAGEMENT CERTIFICATE

Certificate No. 119752-2012-CE-BRA-NA rev 1.0
This Certificate consists of 5 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 production and final product inspection/testing of

Reusable Dental Surgical Instruments and Kits

has, on a voluntary basis, been assessed with respect to

the CAM D conformity assessment procedure , including the requirements for documentation specified in Annex VII, section 3 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

NORWEGIAN ACCREDITATION
Prod002

Aud Løken Eiklid
Certification Manager

Mariann Jeremiassen
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.
This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Certificate history

Revision	Description	Issue Date
	Transfer from another NB (take over)	2012-05-30
1	Recertification	**2012-10-07**

Product Description	Product name and type designation	Class
Bionnovation Instruments Cuttings/ Non-cuttings *(Non-Sterile)*	**Cuttings:** Lindmann drill Twist drill Pilot drill Countersink drill Trephine drill Guide drill Conical drill Spherical drill Screw tap **Non-cuttings:** Hand-held hexed Hand-held driver slot Hand-held driver square Hand-held driver for conical abutment Hand-held driver for spherical abutment Latch-type driver Driver slot for contra-angle Drill extender Hand-held driver lock Driver lock for contra-angle Handpiece conector Simple open wrench Implant depth gauge Prothetic depth gauge Ratchet extension Drive lock for ratchet Depth gauge Parallel pin Driver handle Hexagonal ratchet driver Squared ratchet driver Abutment ratchet driver Slot ratchet driver	I

	O'ring abutment ratchet driver Hand driver Drive lock he td for ratched Titanium grip Rescue driver Prosthetic torque wrench Surgical torque wrench Torque wrench Hexed torque wrench driver Square torque wrench driver Conical/mini conical abutment torque wrench Slot torque wrench driver Spherical abutment torque wrench driver Digital adapter for torque wrench Straight Osteotome Straight Expander Hammer Thread tapper for implant Driver Handle Torque wrench Orthodontic anchor screw Contra-Angle Orthodontic anchor screw Installation rod Screwdriver handle Torque wrench Graft and Fixation Screw Contra-Angle Graft and Fixation Screw	
Instruments – Surgical Kit *(Non-Sterile)*	Lindmann drill Twist drill Pilot drill Countersink drill Trephine drill Guide drill Conical drill Spherical drill Screw tap Hexagonal digital driver Digital driver square Conical abutment/ mini conical digital driver Conical abutment contra-angle driver Spherical abutment digital driver Hexagonal contra angle driver Implant placement adapter for motor driver Drill extender Surgical torque-wrench	I

	Surgical torque-wrench extensor Open and wrench Implant depth gauge Depth gauge pin Parallel pin Mount he Titanium grip Surgical case	
Surgical Kit (Non-Sterile)	Surgical Kit	I
Prosthetic Kit (Non-Sterile)	Prosthetic Kit	I
Summer Osteotome and Expander Kit (Non-Sterile)	Summer Osteotome Kit Expander Kit	I
Orthodontic Kit (Non-Sterile)	Orthodontic Kit	I
Graft and Fixation Screw Kit (Non-Sterile)	Graft and Fixation Screw Kit	I
Cases (Non-Sterile)	Surgical Case Surgical Case Bionnovation II Drill Case Prosthetic Case Orthodontic Case Graft and Fixation Screw Case	I

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

Sites covered by this certificate

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

EU Representative

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.

Declaration and marking of product

This Certificate and the related assessment activities are intended to increase the confidence of the manufacturer and other stakeholders that the requirements of the stated scheme are met.

It is still the full responsibility of the manufacturer to make sure that every product under this Certificate complies with the scheme, and to draw up an EC declaration of conformity and affix the CE mark.

END OF CERTIFICATE