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# DNV BUSINESS ASSURANCE

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## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

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Certificate No. 185089-2015-CE-BRA-NA 0.0

This Certificate consists of 5 pages

*This is to certify that the Quality Management System of*

### **BIODINÂMICA QUÍMICA E FARMACEUTICA LTDA**

Rua Ronat Walter Sodré, 4350 - Parque Ind. IV, 86200-000 Ibiporã - PR, Brazil

*for design, production and final product inspection/testing of*

### **DENTAL MATERIALS**

*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, 06 November 2015

*This Certificate is valid until:*

26 May 2017

For DNV GL BUSINESS ASSURANCE  
NORWAY AS



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Mariann Jeremiassen  
*Certification Manager*

Notified Body No.:  
0434

Aud Løken Eiklid  
*Technical Reviewer*

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://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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 Project No.: PRJ-516549-2014-MSL-BRA

## 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	Original certificate	2015-11-06

## Products covered by this Certificate

Product name	Product description	Model	Class
<b>AUXILIARY DENTAL MATERIAL</b>	Adhesive for Brackets	BIOFIX *Accessory: Applicators Tips	IIa
	Auxiliary material for dental cement	MASTER CEMENT TRY IN *Accessory: Applicator Tips	IIa
	Auxiliary Material for the Instrumentation of the root Canal	ENDO PTC	IIa
	Bonding Agent	SILANO	IIa
	Chelating Agent	E.D.T.A. GEL E.D.T.A. TRISSODIUM	IIa
	Etching Gel	CONDICIONADOR DE PORCELANA *Accessory: Applicators Tips ATTAQUE GEL * Accessory: Applicators Tips	IIa
	Gutta-Percha Solvent	CITROL EUCALIPTOL	IIa
	Hemostatic for Topic Use	HEMOSTANK RETRACTIVE	IIb
	Restorative Dental Ceramic base	BLOCOS DE ZIRCÔNIA	IIa
	Surface Coating	PROVIPLAST GLAZE	IIa
	Temporary Material for Crowns, Bridges and Inlays Onlays	PROVIPLAST *Accessory: Mixing Tips	IIa
<b>PREVENTIVE DENTAL MATERIAL</b>	Calcium Hydroxide Powder	HIDRÓXIDO DE CÁLCIO	IIa
	Cavity Varnish	VARNAL	IIa
	Dentin Desensitizer	G.H.F. DESENSITIZER	IIa



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	Light Cured Calcium Hydroxide	BIOCAL *Accessory: Applicators Tips Biocal MTA	IIa
	Light Cured Glass Ionomer	RESIGLASS F RESIGLASS R *Accessory: White Doser	IIa
	Light Cured Surface Sealant	BIOFORTY	IIa
	Pit and Fissure Sealant	BIOSEAL Light Cured *Accessory: Micro brushe medium BIOSEAL Self Cured BIOSEAL Vitroceramic	IIa
	Self cured Glass Ionomer	BIOGLASS C *Accessory: Orange Doser BIOGLASS F *Accessory: Orange Doser BIOGLASS R *Accessory: Orange Doser	IIa
	Temporary Canal Root Filling Material	HYDROPAST *Accessory: Applicators Tips	IIa
<b>RESTORATIVE DENTAL MATERIALS</b>	Bonding Agent	MASTER BOND *Accessory: Double Applicator Tips black MASTER BOND M.U ULTRABOND	IIa
	Dental Cement	MASTER CEMENT DUAL MASTER CEMENT LC *Accessory: Applicator Tips PERIOLEX	IIa
	Endodontic cement used for filling root canals.	HYDROSEALER N'RICKERT KIT (Powder and Liquid) PULP FILL KIT (Powder and Liquid)	IIa
	Light Cured Composite	EPIC FOTOCLEARMASTER	IIa



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		FILL *Accessory: Applicator tips Micro brush SCULPRESIN ULTRAFILL *Accessory: Applicator Tips Micro brush	
	Light Cured Low Viscosity Composite	MASTER FLOW *Accessory: Applicator Tips	IIa
	Light Cured Temporary Filling material	BIOPLIC	IIa
	Temporary Cement	PROVITEMP *Accessory: Applicator Tips	IIa
	Temporary Restorative Material	EUGENOL FILL TEMP INTERIM KIT (Powder and Liquid) **Accessory: Orange Doser ZINC OXIDE	IIa

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

**Sites covered by this certificate**

Site Name	Address
Biodinâmica Química e Farmacêutica Ltda.	Rua Ronat Walter Sodré, 4350 - Parque Ind. IV, 86200-000 Ibiporã - PR, Brazil

**EU Representative:**

BDP BIODINAMICA DENTAL PRODUCTS LDA  
 Zona Industrial Ladeira da Calça  
 Código Postal: 3260-305 - Figueiró dos Vinhos – Portugal  
 Tel: +351 236.109.015



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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 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