

EC DECLARATION OF CONFORMITY



MANUFACTURER:



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BIODINAMICA QUIMICA E FARMACEUTICA LTDA.

EUROPEAN REPRESENTATIVE: **BDP BIODINAMICA DENTAL PRODUCTS LDA**
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PRODUCT GROUP: **AUXILIARY DENTAL MATERIAL**

PRODUCT NAME / DESCRIPTION / CLASSIFICATION:

PRODUCT NAME	DESCRIPTION	CLASS	RULE	NBOG
ATTAQUE GEL * Accessory: Applicators Tips	Etching Gel with application tips	II a	6	MD0402
BIOFIX *Accessory: Applicators Tips	Adhesive for Brackets	II a	5	MD0402
BLOCOS DE ZIRCÔNIA	Restorative Dental Ceramic base	Ila	8	MD0402
CITROL	Gutta-Percha Solvent	II a	6	MD0402
CONDICIONADOR DE PORCELANA *Accessory: Applicators Tips	Etching Gel	Ila	6	MD0402
E.D.T.A. GEL	Chelating Agent	II a	6	MD0402
E.D.T.A. TRISSODIUM	Chelating Agent	II a	6	MD0402
ENDO PTC	Auxiliary Material for the Instrumentation of the root Canal	II a	6	MD0402
EUCALIPTOL	Gutta-Percha Solvent	II a	6	MD0402
MASTER CEMENT TRY IN *Accessory: Applicator Tips	Auxiliary material for dental cement	II a	6	MD0402
PROVIPLAST Accessory: Mixing Tips	Temporary Material for Crowns, Bridges and Inlays Onlays	II a	7	MD0402
PROVIPLAST GLAZE	Surface Coating	II a	7	MD0402
SILANO	Bonding Agent	Ila	8	MD0402
TUBOS ORTODÔNTICOS	Components for Orthodontics	Ila	5	MD0402

* exclusive use with the product.

** Sterile material

PRODUCT GROUP: **PREVENTIVE DENTAL MATERIAL**

PRODUCT NAME / DESCRIPTION / CLASSIFICATION:

PRODUCT NAME	DESCRIPTION	CLASS	RULE	NBOG
BIOCAL *Accessory: Applicators Tips	Light Cured Calcium Hydroxide	II a	8	MD0402
BIOCAL MTA	Light Cured Calcium Hydroxide	II a	8	MD0402
HIDRÓXIDO DE CÁLCIO	Calcium Hydroxide Powder	II a	8	MD0402
G.H.F. DESENSITIZER	Dentin Desensitizer	II a	8	MD0402
BIOCAL MTA	Light Cured Calcium Hydroxide	II a	8	MD0402
BIOFORTY	Light Cured Surface Sealant	II a	8	MD0402
BIOGLASS C **Accessory: Orange Doser	Self Cured Glass Ionomer	II a	8	MD0402
BIOGLASS F **Accessory: Orange Doser	Self cured Glass Ionomer	II a	8	MD0402
BIOGLASS R **Accessory: Orange Doser	Self cured Glass Ionomer	II a	8	MD0402
BIOSEAL Light Cured *Accessory: Micro brushe medium	Pit and Fissure Sealant	II a	8	MD0402
BIOSEAL Self Cured	Pit and Fissure Sealant	II a	8	MD0402
BIOSEAL Vitroceramic	Pit and Fissure Sealant	II a	8	MD0402
HYDROPAST *Accessory: Applicators Tips	Temporary Canal Root Filling Material	II a	7	MD0303
RESIGLASS F	Light Cured Glass Ionomer	II a	8	MD0402
RESIGLASS R **Accessory: White Doser	Light Cured Glass Ionomer	II a	8	MD0402
VARNAL	Cavity Varnish	II a	8	MD0402

*Applicators Tips: Use purpose: to facilitate the application / product access on the local usage. *exclusive use with the product.*

**Doser: Purpose of Use: set the exact amount of product to be applied; *exclusive use with the product.*

PRODUCT GROUP: **RESTORATIVE DENTAL MATERIAL**

PRODUCT NAME / DESCRIPTION / CLASSIFICATION:

PRODUCT NAME	DESCRIPTION	CLASS	RULE	NBOG
BIOPLIC	Light Cured Temporary Filling material	II a	7	MD0402
EPIC	Light cured composite	IIa	8	MD0402
EUGENOL	Temporary Restorative Material	II a	8	MD0402
FILL TEMP	Temporary Restorative Material	II a	8	MD0402
FOTOCLEAR	Light Cured Composite	IIa	8	MD0402
HYDROSEALER	Endodontic Cement	IIa	8	MD0402

INTERIM KIT (Powder and Liquid) **Accessory: Orange Doser	Temporary Restorative Material	II a	7	MD0402
MASTER BOND *Accessory: Double Aplicator Tips black	Bonding Agent	II a	8	MD0402
MASTER BOND M.U	Bonding Agent	II a	8	MD0402
MASTER CEMENT DUAL	Dental Cement	IIa	8	MD0402
MASTER CEMENT LC *Accessory: Applicator Tips	Dental Cement	IIa	8	MD0402
MASTER FILL *Accessory: applicator tips Micro brush	Light Cured Composite	II a	8	MD0402
MASTER FLOW *Accessory: Applicator Tips	Light Cured Low Viscosity Composite	II a	8	MD0402
N'RICKERT KIT (Powder and Liquid)	Endodontic Cement	II a	8	MD0402
PROVITEMP *Accessory: Applicator Tips	Temporary Cement	II a	7	MD0402
PULP FILL KIT (Powder and Liquid)	Endodontic Cement	II a	8	MD0402
ULTRABOND	Bonding Agent	II a	8	MD0402
ULTRAFILL	Light Cured Low Viscosity Composite	II a	8	MD0402
ZINC OXIDE	Temporary Restorative Material	II a	8	MD0402

* Application Tips - Purpose of use: To facilitate the application/access of the product on the selected area

Doser - Purpose of use: to set the exact product quantity to be applied

Mixing tips - Purpose of use: to homogenize the product and facilitate its application. *exclusive use with the product.*

DECLARATION

BIODINAMICA QUIMICA E FARMACEUTICA LTDA hereby declares that the Quality Management System of the company is in conformance with **EN ISO 13485:2012** and that the medical devices specified above, to which this declaration relates, are in conformance with the essential requirements of **EC Directive 93/42/EEC with annex 2007/47/EEC – Medical Device Directive** and **Brazilian National Legislation**.

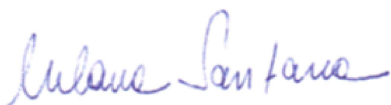
The products have no peculiarities inherent to blood products, animal products and incorporate drugs.

DECLARATION BASED ON: ANNEX II of the **EC Directive 93/42/EEC with annex 2007/47/EEC – Medical Device Directive**.

DECLARATION OF CONFORMITY: Issued by Mrs. Milana Santana, Quality Manager and Mr. Edilson I. Sanches Calvo, Executive President of **BIODINAMICA QUIMICA E FARMACEUTICA LTDA**.

Prepared by: Quality Team.

Date: Aug, 17th, 2015



MILANA SANTANA
Quality Manager



EDILSON I. SANCHES CALVO
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