

EC DECLARATION OF CONFORMITY



MANUFACTURER:

biodinâmica
respect for you

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BIODINAMICA QUIMICA E FARMACEUTICA LTDA.

EUROPEAN REPRESENTATIVE:

BDP BIODINAMICA DENTAL PRODUCTS LDA

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ACCREDITOR:

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PRODUCT GROUP: **AUXILIARY DENTAL MATERIAL**

PRODUCT NAME / DESCRIPTION / CLASSIFICATION:

PRODUCT NAME	DESCRIPTION	CLASS	RULE
ABRASIVE POLYESTER STRIPS DIAMANTEC	Polyester strips for the finishing of inter-proximal areas	I	6
ABRASIVE STEEL STRIPS DIAMANTEC	Stainless steel strips for the finishing of inter-proximal areas	I	6
APPLICATION TIPS	Application Tips	I	1
ARTICULATING PAPER	To register contact areas between antagonist teeth.	I	5
ATTAQUE F *Acessório: Aplicator	Acid Conditioner	I	5
BC CORD	Retraction cord	I	5
BIODAM *Acessório: Bico aplicador	Gingival Barrier	I	5
CONE DE PAPEL	Papel absovente	I	5
CONSIL	Dental Impression Material	I	5
CUTTING ARTICULATED SURGICAL INSTRUMENTS MULTINOX	Surgical Instruments	I	6
CUTTING ARTICULATED SURGICAL INSTRUMENTS ONIX DENT	Surgical Instruments	I	6
CUTTING NON-ARTICULATED SURGICAL INSTRUMENTS MULTINOX	Surgical Instruments	I	6
CUTTING NON-ARTICULATED SURGICAL INSTRUMENTS ONIX DENT	Surgical Instruments	I	6
DIAMOND BURS	Abrasives	I	6
DISPENSER SYSTEM	Application Gun for Dental Materials	I	1

MASCÁRA DESCARTÁVEL BEST CARE	Disposable Insulator	I	1
ELÁSTICOS ORTODÔNTICOS DE LÁTEX BDP	Orthodontic Elastics	I	5
ELÁSTICOS ORTODÔNTICOS DE POLIURETANO BDP	Orthodontic Elastics	I	5
ELÁSTICOS ORTODÔNTICOS SINTÉTICOS BDP	Orthodontic Elastics	I	5
ENDODONTIC INSTRUMENTS NICKEL AND TITANIUM	Endodontic Instruments	I	6
ENDODONTIC INSTRUMENTS ONIXFLEX	Endodontic Instruments	I	6
FIOS ORTODÔNTICOS DE AÇO INOXIDÁVEL BDP	Orthodontics Wire	I	5
FIOS ORTODÔNTICOS DE NI e TI BDP	Orthodontics Wire	I	5
INSTRUMENTOS ODONTOLÓGICOS NÃO CORTANTES	Dental instruments	I	5
INSTRUMENTOS PLÁSTICOS ODONTOLÓGICOS	Dental instruments	I	5
LAMINATOR PLATE Biodinâmica	Plates for trays preparation	I	5
MASTER-BRUSH	Microbrush Applicators	I	5
MATRIZ SECCIONAL ORALTECH	Dental Matrix	I	5
MIXING TIPS	Application tips, which mix components	I	1
NON-CUTTING ARTICULATED SURGICAL INSTRUMENTS MULTINOX	Surgical Instruments	I	6
NON-CUTTING ARTICULATED SURGICAL INSTRUMENTS ONIX DENT	Surgical Instruments	I	6
NON-CUTTING NON-ARTICULATED SURGICAL INSTRUMENTS MULTINOX	Surgical Instruments	I	6
NON-CUTTING NON-ARTICULATED SURGICAL INSTRUMENTS ONIX DENT	Surgical Instruments	I	6
ORALCORD	Retraction cord	I	5
PASTA ABRASIVA DIAMANTADA	Material finishing and polishing	I	5
POSICIONADOR CONE DIAMANTEC	Radiological positioner	I	5
POUCH AND REEL BEST CARE	Sterilization Pouch and Sterilization Reel	I	1
PROPHY-PASTE	Prophylactic Paste	I	5
PROTECTION ORTHODONTIC WAX	Dental Wax	I	5
PUMICE-STONE	Material for Finishing and Polishing	I	5
QUALITYGEL Biodinâmica	Dental Impression Material	I	5
QUALITYGEL ORTHO	Dental Impression Material	I	5
REPLIC	Dental Impression Material	I	5
RETRAFLEX	Retraction cord	I	5
SAFE PACK BEST CARE	Container for sharps and infectious items	I	1
SERINGA DESCARTÁVEL BEST CARE	Syringes	I	2
SODIUM BICARBONATE	Mechanical Remover for Dental Plaque	I	5
SURE CORD	Retraction Cord	I	5
SUGADOR DESCARTÁVEL BEST CARE	Sugador odontológico	I	5
TIRA ABRASIVA DE AÇO	Material finishing and polishing	I	5

TIRA ABRASIVA DE POLIÉSTER COM OXIDO DE ALUMÍNIO	Material finishing and polishing	I	5
WFDFG WANDS	Dental Wedge	I	5

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

PRODUCT GROUP: **PREVENTIVE DENTAL MATERIAL**

PRODUCT NAME / DESCRIPTION / CLASSIFICATION:

PRODUCT NAME	DESCRIPTION	CLASS	RULE
DUAL ARC DISPOSABLE TRAYS FOR FLUORIDE	Dual Arc Disposable Trays for topic fluoride application	I	5

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: Feb 19th, 2015

MILANA SANTANA
 Quality Manager

EDILSON I. SANCHES CALVO
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