

EC DECLARATION OF CONFORMITY



MANUFACTURER:



ADDRESS:

4.350, Ronat Walter Sodré Street
86.200-000 Ibipora Parana Brazil

BIODINAMICA QUIMICA E FARMACEUTICA LTDA.

EUROPEAN REPRESENTATIVE: **BDP BIODINAMICA DENTAL PRODUCTS LDA**
Zona Industrial Ladeira da Calça
Código Postal: 3260-305 - Figueiró dos Vinhos – Portugal
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ACCREDITOR: HEAD OFFICE. Det Norske Veritas AS, Veritasveien 1, 1322
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PRODUCT GROUP: **AUXILIARY DENTAL MATERIAL**
PRODUCT NAME / DESCRIPTION / CLASSIFICATION:

PRODUCT NAME	DESCRIPTION	CLASS	RULE	NBOG
HEMOSTANK	Hemostatic for Topic Use	IIb	6	MD0402
RETRACTIVE	Hemostatic for Topic Use	IIb	6	MD0402

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: March, 30th, 2015

MILANA SANTANA
Quality Manager

EDILSON I. SANCHES CALVO
C.E.O