Bio-Art Equipamentos Odontologicos Ltda

EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC, concerning medical devices

We,

Bio-Art Equipamentos Odontologicos Ltda
Rua Teotonio Vilela, 120 – São Carlos/SP/Brazil – Postal code: 13568-000

declare under our sole responsibility that the following non-sterile products under Class I meet the provisions of the Council Directive 93/42/EEC, concerning medical devices which apply to them:

Articulator (A7 Plus, A7 Fix, 4000-S, EVA Plus and EVA Fix)
Facebow (Standard, Professional and Elite)
Magnifying Lenses (2.5X and 3.5X)
Vacuum Forming Sheet (0.3, 0.6, 1.0, 1.5, 2.0 and 3.0mm)

The products are intended to be used as:

Articulator: is an instrument used to simulate the maxillo-mandibular relation and movements of patients with the purpose of studying occlusion and allow production of dental devices that will be further used by patients. These devices include complete dentures, partial dentures, bridges, crowns and bite plate, among others. The Articulator is used to prosthetic, occlusal and rehabilitation work

Facebow: is an instrument used to register the position of the patient's dental arcade in relation to the skull and transfer this record to the articulator. The Face-Bow is used to construction of complete and partial dentures, bridges, crowns, bite plate, etc.

Magnifying Lenses: is a mechanical/optical device used for magnifying images with purpose to facilitate the visualization of dental procedures in general. The Magnifying Lenses is used to enlarge visualization in direct or indirect procedures.

Vacuum Forming Sheet: is a consumable material used for production of dental trays. It is available in round or square formats and produced with EVA, PET-G and PP laminated polymers. It is used to mouth protector, matrix for composed resin, provisory bridge, copings, whitening etc.

Rua Teotônio Vilela, 120 - Jardim Tangará - CEP 13568-000 - São Carlos - SP - Brasil - Tel. +55 (16) 3371-6502 - www.bioart.com.br

Conformity assessment was performed according to Article 11 (5), Annex VII Section 3 of the Council Directive 93/42/EEC.

The following standards were used to prove the products conformity with the essential requirements of the above directive:

EN 980:2003
EN 1041:1998
EN ISO 13485:2003
EN ISO 14971:2009
ASTM Designation F 899-84
NBR ISO 10993-1:2003
ISO 10993-5:1999
ISO 10993-10:2002

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Obelis s.a.
Registered Address:
53 Bd. Général Wahis
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM

Sao Carlos/SP/Brazil
21/10/2012

Eng. Maria Isabel Piccin
Chief Executive Officer (CEO)

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BIO-ART EQUIPAMENTOS
ODONTOLÓGICOS LTDA.
Rua Teotônio Vilela n.º 120
Jardim Tangará - CEP 13560
SÃO CARLOS – SP

Rua Teotônio Vilela, 120 - Jardim Tangará - CEP 13568-000 - São Carlos - SP - Brasil - Tel. +55 (16) 3371-6502 - www.bioart.com.br