

EC DECLARATION OF CONFORMITY

We,

Bio-Art Equipamentos Odontológicos Ltda,
Rua Teotônio Vilela, 120 – Jd. Tangará
Postal Code: 13568-000
São Carlos/SP - BRASIL
Tel: +55.16.3371.6502 - Fax: +55.16.3372.5953
e-mail: bioart@bioart.com.br

hereby declare under our own responsibility that the following product(s):

- Facebows
- Vacuum forming sheets

meet(s) the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them (it).

The abovementioned device(s) has(ve) been classified as class I devices according to rule 5.

This declaration is supported by the Quality Management System certification:

- **ISO 9001:2008**, certificate TUV.09.21748.0137.15 – First Revision, expires on: 25/01/2022, issued by TÜV Rheinland, local office address: 293 Líbero Badaró St, 9th floor – Center, São Paulo – SP, Zip: 06541-015 - Brazil and,
- **NBR ISO 13485:2004**, certificate TUV.13.21748.0138.15 – First Revision, expires on: 01/02/2022, issued by TÜV Rheinland, local office address: 293 Líbero Badaró St, 9th floor – Center, São Paulo – SP, Zip: 06541-015 - Brazil.

This declaration is based on the conformity assessment of products to the requirements of Annex VII Section 3 and Article 11 (5) of the Council Directive 93/42/EEC.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled “Manufacturer”.

Sao Carlos, SP, Brazil, 22/04/2019



MBA - Eng. Maria Isabel Piccin (CEO)
BIO-ART Equipamentos Odontológicos Ltda

58538372/0001-56

BIO-ART EQUIPAMENTOS
ODONTOLÓGICOS LTDA,

Rua Teotônio Vilela n.º 120
Jardim Tangará - CEP 13560

SÃO CARLOS - SP

European Authorized Representative:

Registered Address:

Obelis s.a.

Bd. Général Wahis 53

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 (CEO)