

EC DECLARATION OF CONFORMITY
(MSD 2006/42/EC, Annex II, 1, A)

Manufacture's Name: BIO-ART EQUIPAMENTOS ODONTOLÓGICOS LTDA

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Person authorized to compile the Technical File, established in the Community: Obelis S.A. (see address above)

Description of the machinery:

Bio-Chamber:

- **Short product description:** The Bio-Chamber is a device equipped with exhaustion system, exclusively designed for work with the Microblaster, and assures more cleanness, providing efficiency, safety and functionality during the blasting process.
- **Intent of use:** exhaustion of aluminium oxide during the blasting process.
- **Mode of operations:** The Bio-Chamber is operated manually.



Hairbrushes Sanitizer Standard and Plus (Shiva):

- **Short product description:** The Hairbrushes Sanitizer is a new concept mechanical/electrical equipment developed for beauty area whose purpose is sanitize hairbrush, combs and accessories through hot steam.
- **Intent of use:** Sanitization of hairbrush, combs and accessories.
- **Mode of operations:** The Hairbrushes Sanitizer is operated manually.

Milling Machine 1000N:

- **Short product description:** The Milling Machine 1000N is a mechanical device which enables determining the relative parallelism between the teeth surfaces and also carry out milling procedures and adjustments on dental prostheses.
- **Intent of use:** The Milling Machine 1000N is used for planning and milling dental prostheses.
- **Mode of operations:** The Milling Machine 1000N is operated manually by the dental professional.

Sealing Machine Biostamp:

- **Short product description:** The Sealing Machine is a mechanical/electrical equipment developed and used for sealing surgical papers.
- **Intent of use:** Sealing surgical papers with the purpose to pack instruments for further sterilization in autoclave.
- **Mode of operations:** The Sealing Machine is manually operated by the dental professionals.

Washing Machine Biowash STD:

- **Short product description:** The Washing Machine is a mechanical/electrical equipment developed and used for ultrasonic cleaning process.
- **Intent of use:** Washing and cleaning prosthesis and instruments in general.
- **Mode of operations:** The Washing Machine is manually operated and with electronic programming operation time.

Surveyor B2:

- **Short product description:** The surveyor is a mechanical device which allows determining the relative parallelism between two or more teeth surfaces or other parts of a dental arch model.
- **Intent of use:** The Surveyor is used to plan dental prosthesis.
- **Mode of operations:** The Surveyor is operated manually by the dental professional.

Vacuum Forming Machine Plastvac P7 and P7 Plus:

- **Short product description:** The Plastvac P7 is a mechanical/electrical device used for production of trays through plasticizing of dental models/casts. The process is simple and basically consists on heating and vacuum forming the sheet.
- **Intent of use:** Mouth protector, matrix for composed resin, provisory bridge, copings, surgical guides, bite plate (bruxism), whitening, etc...
- **Mode of operations:** Mouth protector, matrix for composed resin, provisory bridge, copings, surgical guides, bite plate (bruxism), whitening, etc...

Microblaster Lab:

- **Short product description:** The Microblaster is a portable pneumatic device of easy installation and operation, developed for blasting.
- **Intent of use:** blasting of surfaces with aluminium oxide
- **Mode of operations:** The Microblaster is operated manually.

Directive(s) Complied with: European Council Directive on the Safety of Machine 2006/42/EC

European Harmonized Standards to which Conformity is Declared:

IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements;

IEC 61010-2-10 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials;



IEC 60335-1 - Household and similar electrical appliances - Safety - Part 1: General requirements;

IEC 60335-2-15 - Household and similar electrical appliances - Safety - Part 2-15: Particular requirements for appliances for heating liquids;

IEC 61000-4-2 - Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test;

IEC 61000-4-4 - Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test;

IEC 61000-4-5 - Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test;

IEC 61000-4-6 - Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields;

IEC 61000-4-11 - Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests;

IEC 60695-2-11 - Fire hazard testing - Part 2-11: Glowing/hot-wire based test methods - Glow-wire flammability test method for end-products;

CISPR 14-1 - Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission.

We, the undersigned hereby, declare that the machinery specified above fulfills all the relevant provisions of the European Council Directive 2006/42/EC, Low Voltage Equipment 2006/95/EC and Electromagnetic Compatibility 2004/108/EC).

Sao Carlos/SP/Brazil (23/02/2017)



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