



BIO-ART EQUIPAMENTOS ODONTOLOGICOS LTDA
Rua Teotônio Vilela, 120, São Carlos/SP 13568-000 Brazil

DICHIARAZIONE DI CONFORMITA'

(MSD 20006/42/EC, Annex II, 1, A)

Si dichiara sotto la propria esclusiva responsabilità che il dispositivo sottostante soddisfa tutte le disposizioni della Direttiva Europea 2006/42/EC, Apparecchiature a basso voltaggio 2006/95/EC, Compatibilità Elettromagnetica 2004/108/EC

Apparecchiatura: Sigillatrice manuale a funzionamento meccanico/elettrico utilizzata per la saldatura di carta medicale nella sterilizzazione di strumentario chirurgico in autoclave.

Matricola nr.:

Responsabile Europeo Autorizzato:

Obelis S.A - Boulevard Général Wahis 53, B-1030 Brussels, Belgium (tel: 32 (0) 2 7325954

Norme Europee armonizzate utilizzate per dichiarare la conformità:

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

IEC 61010-2-10 Safety requirements for eletrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for the 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 the laboratory equipment for the heating of materials; **IEC 61000-4-2** Elettromagnetic compatibility (EMC) – Part 4-2: Testing and measurement tecqhniques – Eletrostatic discharge immunity test; **IEC 61000-4-4** Elettromagnetic compatibility (EMC) – Part 4-4: Testing and measurement tecqhniques – Eletrical fast transient/burst immunity test; **IEC 61000-4-4** Elettromagnetic compatibility (EMC) – Part 4-5: Testing and measurement tecqhniques – Surge immunity test ; **IEC 61000-4-6** Elettromagnetic compatibility (EMC) – Part 4-6: Testing and measurement tecqhniques – Immunity to conducted disturbances, induced by radio-frequency fields;

IEC 61000-4-11 Elettromagnetic compatibility (EMC) – Part 4-11: Testing and measurement tecqhniques – Voltage dips, short interruptions and voltage variations immunity test ; **IEC 60695-2-11** Fire hazard testing – Part 2-11: Glowing/hot-wire based test methods – Glow-wire flammability trest method for end-products; **CISPR 14-1** – Elettromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission

Questa dichiarazione è valida a partire dal 22 Novembre, 2012.

Responsabile della presente dichiarazione:

Bio-Art Equipamentos Odontologico Ltda - Rua Teotônio Vilela, 120, São Carlos/SP 13568-000 Brazil

Sao Carlos/SP/Brazil (22/11/2012)

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