

Declaration of Conformity

**Manufacturer:
(Name & Address)** Inovo Inc.
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Notified Body: BSI Assurance UK Limited (Milton Keynes)
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**Authorized
Representative:** MDSS GmbH
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Inovo Inc. hereby declares that the product(s) specified below have been designed, manufactured, inspected, labeled and distributed in accordance with the applicable provisions of the EC Directive 93/42/EEC, as stated in Annex II without Section 4.

Product Name: Bonsai Oxygen Conserving Device

Model: OM-810CE
OM-812
OM-824

Classification: Class IIb / Rule 11

Applicable Standards: Please refer to the Summary Technical Document for the listing of all applicable standards.

This Declaration of Conformity covers all medical devices as specified in the above product list belonging to this declaration and is only valid in connection with a batch specific list for all products concerned and bearing the CE 0086 mark. This Declaration of Conformity is within conformance to the 2007/47/EEC amendment.

Approval:

Signature: 
Sandy Figueroa / Regulatory Affairs Manager

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