

Declaration of Conformity

Manufacturer: Inovo Inc.
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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 and conforms with RoHS 2, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Product Name: Evolution Oxygen Conserver

Model: OM-900CE
OM-900M
OM-924
OM-950

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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