Declaration of Conformity

Manufacturer:
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Inovo, Inc. hereby declares that the product(s) specified below have been designed, manufactured, inspected and distributed in accordance with the applicable provisions of the EC Directive 93/42/EEC, as stated in Annex II w/o Sect. 4

Product: Evolution Oxygen Conserver

Model(s): OM-900CE, OM-900, OM-922, OM-923, OM-924, OM-925, OM-900M, OM-922M, OM-923M, OM-924M, OM-925M, OM-950

Classification: Class IIb/Rule11 of Annex IX, MDD

Applicable Standards:

EN ISO 13485:2012	EN ISO 13485:2012/AC:2012
EN ISO 14971:2012	EN 60601-1-2:2007/AC:2010
EN ISO 18779:2005	EN 1041: 2008
EN ISO 10524-1: 2006	EN ISO 15001:2011
EN 980 2008	EN ISO 10993-1: 2009
EN 60601-1:2005	EN 62366:2008
EN 62304:2006/AC2008	EN 60601-1-11:2010

Approval:

Michael Wojnovich
Director, Quality Assurance
Management Representative

Issue Date: ***November 1, 2015***

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration for Model No's OM-900CE, OM-900, OM-922, OM-923, OM-924, OM-925, OM-900M, OM-922M, OM-923M, OM-924M, OM-925M, OM-950 and is only valid in connection with a batch specific packing list for all products concerned bearing the CE 0086 mark.
This Declaration of Conformity is in conformance with the 2007/47/EC amendment.