Declaration of Conformity

Manufacturer:
Inovo, Inc.
401 Leonard Blvd. North
Lehigh Acres, Florida 33971
USA

Notified Body:
BSI Milton Keynes
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hanover, Germany
49- 511- 6262- 8630

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: Oxygen Conserving Device

Model: Models OM-810, OM-810CE, OM-822, OM-823, OM-824, OM-825

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 ISO 15001:2011
EN ISO 18779:2005	EN 980:2008
EN ISO 10524-1:2006	EN 1041:2008
IEC 60068-2-27:2008	EN ISO 10993-1:2009-AC:2010
EN 62366: 2008	

Approval:

Michael T. Dildine
Director, Quality Assurance
Management Representative

Issue Date: **March 11, *2015***

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration(Model No's OM-810, OM-810CE, OM-822, OM-823, OM-824 and OM-825) 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.