

## Declaration of Conformity

**Manufacturer:** Inovo, Inc.  
2975 S. Horseshoe Dr.  
Naples, FL. 34104

**Notified Body:** TUV Rheinland  
Product Safety GmbH (0197)

**Authorized Representative:** MDSS  
Schiffgraben 41  
30175 Hanover, Germany

---

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.3

**Product:** Lotus Electronic Conserving Regulator

**Model:** Models 700, 700S and 700J

**Classification:** Class IIa/Rule11 of Annex IX, MDD

**Applicable Standards:**

EN ISO 13485:2003	EN 60601-1: 1990+A1+A2+A13
EN ISO 14971:2007	EN 60601-1-2:2001
EN ISO 18779:2005	EN 1041: 1998
EN ISO 10524-1: 2006	IEC 61000-4-2: 1994+A1
EN ISO 15001:2004	IEC 61000-4-3: 1995+A1
EN 980 2008	IEC 68-2-27:1987
EN ISO 4135: 2001	EN 60601-1-4:1996+A1
Mil Std 461E: 1999	EN 60601-1-6 : 2004

**Approval:**



**Michael T. Dildine**  
Director of Quality Assurance  
Management Representative

**Issue Date:** *February 27, 2009*

2975 Horseshoe Drive South, Suite 600  
Naples, FL 34104

Toll-Free: 888-446-6862 Fax: 239-643-6530  
ISO 13485 Registered

**inovo**

[www.inovoinc.com](http://www.inovoinc.com)

**CHAD**<sup>®</sup>  
therapeutics

[www.chadtherapeutics.com](http://www.chadtherapeutics.com)