

# Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
ClearVue Prone Breast Treatment Table	OT-2-1000 Note: D, O, or U suffix indicates configuration.

MANUFACTURER		
Name of company	Address	Representative
Orbital Therapy, LLC	8 Alfred Circle Bedford, MA 01730 United States of America	Natalya Koshnitsky

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class I Rule 1	Annex 7 of MDD 93/42/EEC Council Directive	EN ISO 14971:2007 EN 60601-1: 2005 Section 9 (mechanical hazards) EN 980:2008 EN 1041:2008

Orbital Therapy, LLC declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Jason Koshnitsky

**TITLE:** President and Chief Executive Officer

**SIGNATURE:**



**DATE:** 2/10/2009