

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
ultraStand Probe Positioning System	B1P1R1F1H1 B2P1R1F1H1 B3R1F1H1 B4R1F1H1

MANUFACTURER		
Name of company	Address	Representative
Wellan Medical	10 Water Street Lebanon, NH 03766 USA	R.T.A. van Aalst

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 1 Rule 1	Annex VII of MDD 93/42/EEC Council Directive	EN 980:2003 EN 1041:1998 EN ISO 14971:2000 + A1:2003

Wellan Medical declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

COMPANY REPRESENTATIVE: R.T.A. van Aalst

TITLE: Vice President **SIGNATURE:**

DATE: 14/12/2007

