Declaration of Conformity

Welch Allyn

Number:	60031770_C
Manufacturer: Address:	Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153-0220 USA
Manufacturing site	Welch Allyn de Mexico S. de R.L. de C.V. Calle Emilio Flores #271-A Colonia Cañon de Padre Tijuana, Baja California C.P. 22203 Mexico
Representative: Address:	European Regulatory Representative, Welch Allyn Ltd. Navan Business Park, Dublin Road, Navan, County Meath, Republic of Ireland Tel. +353 46 9067700 Fax. +353 46 9067755

We Welch Allyn declare under our sole responsibility that the Product

Name:	**GS 300**	
Model Number:	44400	GS300 General Exam light with Mobile Stand DOM
	44452	GS300 General Exam light with Mobile Stand EUR
	44454	GS300 General Exam light with Mobile Stand UK
	44456	GS300 General Exam light with Mobile Stand AU
	44457	GS300 General Exam light with Mobile Stand ZA
	44458	GS300 General Exam light with Mobile Stand CN
	44410	GS300 General Exam light with Table/Wall Mount DOM
	44412	GS300 General Exam light with Table/Wall Mount EUR
	44414	GS300 General Exam light with Table/Wall Mount UK
	44416	GS300 General Exam light with Table/Wall Mount AU
	44417	GS300 General Exam light with Table/Wall Mount ZA
	44418	GS300 General Exam light with Table/Wall Mount CN
Accessory	48955	Table/Wall mount for GS Exam Light Iv/GS300/GS600

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To which this declaration relates is in conformity with the following standards

EN 14971: 2007	Medical Devices- Application of Risk Assessment to medical devices
EN 60601-1: 1990 (incl. amendments)	Medical Electrical Equipment- part 1: General requirements for basic safety and essential requirements
EN 60601-1-1: 2000	Medical Electrical Equipment- part 1-1-General requirements for safety- Collateral Standard: Safety requirements for Medical Electrical Equipment
EN 60601-1-2: 2004	Medical Electrical Equipment- part 1-2- General requirements for safety- Collateral Standard: Electromagnetic Compability- Requirements and Test
EN 60601-1-4: 1997	Medical Electrical Equipment- part 1-4- General requirements for safety- Collateral Standard: General requirements for programmable electrical medical systems
EN 60601-1-6: 2004	Medical Electrical Equipment- part 1-6- General requirements for safety- Collateral Standard: Usability
EN 1041: 2008	Information supplied by the manufacturer with Medical devices
EN 980: 1997	Graphical symbols for use in the labeling of medical devices

The quality system that controls the manufacture of this product complies with the following standards, EN ISO 13485:2003.

Following the provisions of European Council Directive 93/42/EEC of 14 June1993 concerning medical devices Annex VII. Device is Class I under rule(s) 12 of Annex IX of this directive and following the provisions of European Council Directive 2006/95/EC of 12 December 2006 concerning electrical equipment designed or used within certain voltage limits.

European Regulatory Representative

Signed: _____
Paul Reynolds

Place of issue, Welch Allyn Ltd. Ireland.

Date: 2009-12-16