Welch Allyn Australia (Pty) Ltd.
Unit 5, 38 – 46 South Street
Rydalmere NSW 2116

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.: 80020236 Version: A

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Welch Allyn, Inc.
Business address:	4341 State Street Road Skaneateles Falls, NY 13153-0220 U.S.A.
Product name:	GS Lights
#	DEVICES: 44416, 44456, 44606, 44616, 44906, 44900-C, 44900-W, 48816 ACCESSORIES: 44215, 48200, 48605, 48805, 48850, 48950, 48955, 48960, 52630, 52640-B, 405966
Classification:	I
GMDN code and term:	12276 – Light, examination
Scope of application:	All

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

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Standards applied:	EN 14971	2007	Medical Devices- Application of Risk Assessment to medical devices
	EN 60601-1 (incl. Amendments)	1990	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	2008	Graphical symbols for use in the labeling of medical devices
	EN 62366	2008	Medical devices- Application of usability engineering to medical devices
	ISO 14155	2003	Clinical investigation of medical devices for human subjects
	ISO 10993-1	2003	Biological evaluation of medical devices -- Part 1: Evaluation and testing

Authorised Signatory:

Tim Croft Sr. Manager, Regulatory Affairs - JAPAC

2015-09-21
Date

Rydalmere, NSW
Place of Issue

This authorisation is given in the signatory's capacity as representative of the "Manufacturer" (as recorded on page 1 of this declaration)