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.:	80020741	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 777 Wall Transformer
#	77716
Classification:	I
GMDN code and term:	36545 – Power supply, general purpose
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 980	2008	Graphical Symbols for Use in the Labelling of Medical Devices
	EN 1041	2008	Information Supplied by the Manufacturer with Medical Devices
	IEC 60601-1 2nd Edition	1988	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
	IEC 60601-1 3rd Edition	2005	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
	IEC 60601-1-2	2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
	IEC 60601-1-6	2010	Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	IEC 62366	2007	Medical Devices - Application of Usability Engineering to Medical Devices.
	ISO 13485	2003	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	ISO 14155	2011	Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice
	ISO 14971	2009	Medical Devices - Application of Risk Management to Medical Devices
	ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	ISTA 2A	2011	Packaged-Products 150 LB (68 KG) or less

Authorised Signatory:

Tim Croft Sr. Manager, Regulatory Affairs - JAPAC 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)

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Document Change History

Version	Description	Author	Date
A	Initial release		