

# MANUFACTURER'S DECLARATION OF CONFORMITY AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002 DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.:	80020741	Version:	Α				
This is a declara Devices) Regula		y made under cla	use 6.6 of Schedule 3 to the Therapeutic Goods (Medical				
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							
#	77	716					
Classification: I							
GMDN code and	d term: 365	: 36545 – Power supply, general purpose					
Scope of application: All							
			l documentation applies complies with the applicable fication 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	Info	ormation Supplied by the Manufacturer with Medical Devices		
		IEC 60601-1 2nd Edition	1988		dical Electrical Equipment - Part 1: General Requirements for ic 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	Bas	dical Electrical Equipment – Part 1-2: General Requirements for ic Safety and Essential Performance - Collateral Standard: ctromagnetic Compatibility - Requirements and Tests		
		IEC 60601-1-6	2010	basi	dical Electrical Equipment - Part 1-6: General requirements for ic safety and essential performance - Collateral standard: bility		
		IEC 62366	2007		dical Devices - Application of Usability Engineering to Medical vices.		
		ISO 13485	2003		dical Devices - Quality Management Systems - Requirements for gulatory Purposes		
		ISO 14155	2011		nical Investigation of Medical Devices for Human Subjects - od Clinical Practice		
		ISO 14971	2009		dical Devices - Application of Risk Management to Medical vices		
		ISO 10993-1	2009		logical evaluation of medical devices - Part 1: Evaluation and ing within a risk management process		
		ISTA 2A	2011	Pac	kaged-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
А	Initial release		