



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.:	80019862	Version:	B
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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. 4341 State Street Road Skaneateles Falls, NY 13153-0220
Business address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153-0220
Product name:	KleenSpec® Illumination System
<b>REF</b>	901070 Vaginal Speculum Lighting System
<b>#</b>	78816, 79916, 79926
Classification:	I Per classification rules 3.1 and 4.1 as defined in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002
GMDN code and term:	12340 – Light source
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/IEC 60601-1	1990/1988 +A1:1991, +A2:1995, +A13:1996	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
	EN/IEC 60601-1-2	2007/2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
	EN/IEC 60601-1-6	2004/2004	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	IEC 60601-1-6	2010	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
	EN 1041	2008	Information supplied by the manufacturer with medical devices
	EN/ISO 10993-1	2009/2009	Biological Evaluation of Medical Device – Part 1: Evaluation and Testing
	IEC 62281	2012	Safety of primary and secondary lithium cells and batteries during transport
	EN/IEC 60086-4	2007	Primary batteries. Safety of lithium batteries

Authorised Signatory:

\_\_\_\_\_ Rydalmere, NSW  
Tim Croft Sr. Manager, Regulatory Affairs - JAPAC Date 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 – transferred from DIR 80016895	Tim Croft	2014-11-21
B	Removed components & non-medical accessories	Tim Croft	2015-10-06