


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

SAP DIR No.:	80020830	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:	Laryngoscope LED Lamp
	06000-LED
Classification:	1
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.

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

SAP DIR No.:	80020830	Version:	A
--------------	----------	----------	---

Standards applied:	EN ISO/ISO 13485	2012/2ED 2003	MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS FOR REGULATORY PURPOSES
	EN ISO/ISO 14971	2012/2ED 2007 CORRECTED	MEDICAL DEVICES - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
	EN ISO/ISO 7376	2009/2ED 2009	ANAESTHETIC AND RESPIRATORY EQUIPMENT - LARYNGOSCOPES FOR TRACHEAL INTUBATION
	EN/IEC 60601-1	1990, AMD 1, AMD 2, AMD 11, AMD 12, AMD 13/2ED 1988, AMD 1 1991, AMD 2 1995	MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
	EN/IEC 60601-1	2006 AMD 11 2011, AMD 1 2013/3ED 2005, AMD 1 2012	MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
	EN/IEC 60601-1-2	2007/3ED 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	2004/1ED 2004	MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY
	EN/IEC 60601-1-6	2010/3ED 2010	MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY
	ISTA 1A	2001	PACKAGED-PRODUCTS 150 LB (68 KG) OR LESS

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)

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

<i>SAP DIR No.:</i>	80020830	Version:	A
---------------------	----------	----------	---

Document Change History

Version	Description	Author	Date
A	Initial release	Tim Croft	2015-09-30