

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

SAP DIR No.:	80021366	Version:	A
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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.
Business address:	4341 State Street Road Skaneateles Falls, NY 13153-0220 U.S.A.
Product name:	Fiber-optic Laryngoscope Blades
REF	901038 LARYNGOSCOPE
#	68060, 68061, 68062, 68063, 68064, 68065, 69061, 69062, 69063, 69064, 69211, 69212, 69213, 69214.
Classification:	1
GMDN code and term:	46827 - Laryngoscope blade, reusable
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.

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



Welch Allyn Australia (Pty) Ltd.
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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:



Kevin Crossen, Director Global Regulatory Affairs

2016-03-04
Date

Skaneateles Falls, NY USA
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)