

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

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

**Medical device(s):** Fiber-optic Laryngoscope  
#: 901038 Laryngoscope  
  
Fiber-optic Laryngoscope Blades  
#: 901038 Laryngoscope  
  
See Appendix I for List

**Classification:** Class I

**GMDN code and term:** 15076 – Rigid intubation laryngoscope, reusable  
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.

**Full quality assurance procedures certificate:** 314505 MP2016

**Standards applied:**

Standard	Version	Title
EN ISO/ISO 13485	2016	MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS FOR REGULATORY PURPOSES
EN ISO/ISO 14971	2012	MEDICAL DEVICES - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
EN ISO/ISO 7376	2009/2ED 2009	ANAESTHETIC AND RESPIRATORY EQUIPMENT - LARYNGOSCOPES FOR TRACHEAL INTUBATION NOTE: Compliance report available for catalog numbers ending in -LED.
EN/IEC 60601-1	2013	MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
EN/IEC 60601-1-2	2015	MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS



**Standards applied:**

Standard	Version	Title
EN/IEC 60601-1-6	2015	MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY
EN 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 61951-1	2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Portable sealed rechargeable single cells Part 1: Nickel-cadmium
62133-1	2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel system
EN10993-10	2013	Biological evaluation of medical devices_ - Part_10: Tests for irritation and skin sensitization
EN10993-1	2001-10	Biological evaluation of medical devices_ - Part_1: Evaluation and testing within a risk management process
EN10993-5	2009	Biological evaluation of medical devices_ - Part_5: Tests for in vitro cytotoxicity
EN/ISO 17664	2017	Processing of health care products- Information to be provided by the medical device manufacturer for the processing of medical devices.
EN/ISO 14155	2011	Clinical investigation of medical devices for human subjects- Good clinical practice

**Authorised signatory:**


Joshua Kim  
Senior Manager, Regulatory Affairs



Date



Part number (REF)	Description	GMDN
696005-1	LARYNGOSCOPE	15076
68040	#0 MIL ASTM LARYNGOSCOPE	15076
68041	#1 MIL ASTM LARYNGOSCOPE	15076
68042	#2 MIL ASTM LARYNGOSCOPE	15076
68043	#3 MIL ASTM LARYNGOSCOPE	15076
68044	#4 MIL ASTM LARYNGOSCOPE	15076
68045	00 MIL ASTM LARYNGOSCOPE	15076
68060	#0 MIL F/O LARYNGOSCOPE	15076
68061	#1 MIL F/O LARYNGOSCOPE	15076
68062	#2 MIL F/O LARYNGOSCOPE	15076
68063	#3 MIL F/O LARYNGOSCOPE	15076
68064	#4 MIL F/O LARYNGOSCOPE	15076
68065	#00 MIL F/O LARYNGOSCOPE	15076
69041	#1 MAC ASTM LARYNGOSCOPE	15076
69042	#2 MAC ASTM LARYNGOSCOPE	15076
69043	#3 MAC ASTM LARYNGOSCOPE	15076
69044	#4 MAC ASTM LARYNGOSCOPE	15076
69061	#1 MAC F/O LARYNGOSCOPE	15076
69062	#2 MAC F/O LARYNGOSCOPE	15076
69063	#3 MAC F/O LARYNGOSCOPE	15076
69064	#1 E-MAC F/O LARYNGOSCOPE ASSY	15076
69211	#2 E-MAC F/O LARYNGOSCOPE ASSY	15076
69212	#3 E-MAC F/O LARYNGOSCOPE ASSY	15076
69213	#4 E-MAC F/O LARYNGOSCOPE ASSY	15076
69214	#1 E-MAC LAMP LARYN. ASSY	15076
69241	#2 E-MAC LAMP LARYN	15076
69242	#2 E-MAC LAMP LARYN	15076
69243	#3 EMAC LAMP LARYNGOSCOPE	15076
69244	#4 EMAC LAMP LARYNGOSCOPE	15076
68096	F/O LARYNGOSCOPE SET-MILLER	15076
68696	F/O LARYNGOSCOPE SET-MILLER W/LED	15076
68696-LED	F/O LARYNGOSCOPE SET-MILLER W/LED	15076
69096	STANDARD MAC LARYN SET	15076
69097	STD LARYNGOSCOPE SET E-MAC	15076
69696	F/O LARYNGOSCOPE SET-MAC	15076



69696-LED	F/O LARYNGOSCOPE SET-MAC W/LED	15076
69697	F/O LARYNGOSCOPE SET-E MAC	15076
69697-LED	F/O LARYNGOSCOPE SET-E MAC W/LED	15076
680133-501	#1 MAC STD LT PIPE ASSY	15076
680133-503	#3 MAC STD LT PIPE ASSY	15076
680133-504	#4 MAC STD LT PIPE ASSY	15076
680134-501	#1EMAC LT PIPE W/MK BASE,WIRED	15076
680134-502	#2EMAC LT PIPE W/MK BASE,WIRED	15076
680134-503	#3EMAC LT PIPE W/MK BASE,WIRED	15076
686014-1	F/O LITE PIPE MIL#0 FINISHED	15076
686018-1	F/O LITE PIPE MIL#4 FINISHED	15076