

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
REF: 901038 Laryngoscope

Fiber-optic Laryngoscope Blades
REF: 901038 Laryngoscope

Fiber-optic Laryngoscope Battery Handle
REF: 901087 Instrument Handle

Classification: Class I

GMDN code and term: 15076 – Rigid intubation laryngoscope, reusable
46827 – Laryngoscope blade, reusable
46830 – Laryngoscope handle, 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 MP2012

Standards applied:

Standard	Version	Title
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 NOTE: Compliance report available for catalog numbers ending in –LED.

Standards applied:

Standard	Version	Title
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	4ED 2014-02-25	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:



Joshua Kim
Senior Manager, Regulatory Affairs

2019.03.07
Date