DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name[1,3]:	Fiber Optic Laryngoscopes
REF [1,3]	901038, LARYNGOSCOPE 901087, INSTRUMENT HANDLE
# [1,3]	Blades: 68060, 68061, 68062, 68063, 68064, 68065 (Miller Fiber-Optic Blades) 69061, 69062, 69063, 69064 (MacIntosh Fiber-Optic Blades) 69211, 69212, 69213, 69214 (English MacIntosh Fiber-Optic Blades) Handles: 60813, 60813-LED, 60814, 60814-LED, 60815, 60815-LED, 60713, 60835 (Fiber Optic Battery Handles) Kits: 65122, 68696, 68696-LED, 69696, 69696-LED 69697 & 69697-LED
Radio equipment[2]:	Not Applicable, no radio
Object of the declaration[2]:	Not Applicable, no radio
Accessories and components[2]:	Not Applicable, no radio
Medical Device Conformity Assessment Route Annex[1]:	VII

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU

Medical Device Classification[1]:	I	
Medical Device Classification Rules[1]:	5	
GMDN Code and Term[1]:	15076 - Rigid intubation laryngoscope, reusable	
UMDNS Code and Term[1]:	15076 - Laryngoscopes designed with a non-flexible (i.e., rigid) structure that can only follow a straight path through the airway. They are constructed of metal and contain straight or curved blades for manipulation of the tongue and pharynx during the procedures. Rigid endoscopes are frequently used for insertion of endotracheal tubes.	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title
	EN 50581[3]	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN / IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
	EN/IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
	EN/IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
	EN/IEC 62366	Medical Devices - Application of Usability Engineering To Medical Devices
	ISO 7376-3	Laryngoscope fittings - Part 3: Fibre-illuminated re-usable rigid laryngoscopes
	EN / ISO 7376	Anaesthetic and respiratory equipment -- Laryngoscopes for tracheal intubation NOTE: Compliance report applicable to blades used with –LED handles.
	EN / ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

Authorised Signatory:

Fiona Butler — 2019-05-15 — Navan

Fiona Butler, Manager Regulatory Affairs | Date | Place of Issue

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU