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]:	Digital MacroView™ Otoscope
REF [1,3]	901001, ACCESSORY, EYE, EAR NOSE & THROAT 901021, OTOSCOPE, WIDEVIEW
# [1,3]	22002, 22003, 22004, 22005, 22009, 22100, 22120, 23804, 24320, 24320-B, 24330, 24330-B, 24302-U, 24303-U, 24304-U, 24305-U, 24400-U, 52432-U, 52432-UB, 52434-U, 52434-UB, 52450-S, 23920, 23921
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
Medical Device Classification[1]:	I
Medical Device Classification Rules[1]:	5 and 12

[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

GMDN Code and Term[1]:	12849 Otoscope, direct	
UMDNS Code and Term[1]:	12849 Otoscope	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety.
	EN/IEC 60601-1-2	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
	IEC 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
	IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

Authorised Signatory:

Fiona Butler — 2018-10-02 — Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | 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