# DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

*SAP DIR No.:* 80017158 Version: J

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)

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| Manufacturer's Name and Business Address: | Welch Allyn, Inc.<br>4341 State Street Road<br>Skaneateles Falls, NY 13153, USA |
| EC REP | Regulatory Affairs Representative<br>Welch Allyn Limited<br>Navan Business Park<br>Dublin Road<br>Navan, County Meath<br>Republic of Ireland |
| Product Name: | Digital MacroView™ Otoscope |
| REF | 901001, ACCESSORY, EYE, EAR NOSE & THROAT<br>901021, OTOSCOPE, WIDEVIEW |
| # | 22002, 22003, 22004, 22005, 22009, 22100, 22120, 23804, 24320, 24330, 24302-U, 24303-U, 24304-U, 24305-U, 24400-U, 52432-U, 52432-UB, 52434-U, 52434-UB, 52450-S, 23920, 23921 |
| Medical Device Conformity Assessment Route Annex: | VII |
| Medical Device Classification: | I |
| Medical Device Classification Rules: | 5 and 12 |
| GMDN Code and Term: | 12849 – Otoscope, direct |
| UMDNS Code and Term | 12849 – Otoscope |
| Standards Applied: | EN 50581 — Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |

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| 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

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2017-09-22
Date

Navan
Place of Issue