

Welch Allyn® 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)

Manufacturer's Name and Business Address: Welch Allyn, Inc.
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Skaneateles Falls, NY 13153, USA



Regulatory Affairs Representative
Welch Allyn Limited
Navan Business Park
Dublin Road
Navan, County Meath
Republic of Ireland

Product Name: Digital MacroView™ Otoscope



901001, ACCESSORY, EYE, EAR NOSE & THROAT
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, Manager Regulatory Affairs
{EU Authorised Representative}

2017-09-22

Date

Navan
Place of Issue