

# 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.  
4341 State Street Road  
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}

Date

Navan  
Place of Issue