

# Welch Allyn® DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016526 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  
U.S.A.



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

Product Name: Otoscope



901079 OTOSCOPE, STANDARD  
901080 OTOSCOPE, POCKET  
901021, OTOSCOPE, WIDEVIEW



20000, 20000-L, 20001, 20097, 20098, 20200, 20201, 20203, 20250, 20251, 20270, 20282, 20283, 20284, 20285, 21110, 21111, 21140, 21141, 21307, 21308, 21504, 21700, 21701, 21770, 21782, 21783, 21784, 21785, 22009, 22091, 22100, 22800, 22811, 22820, 22821, 22822, 22831, 22840, 22841, 22860, 22861, 22870-BLK, 22870-BLU, 22870-PUR, 22870-WHT, 22880-BLK, 22880-BLU, 22880-PUR, 22880-WHT, 23510, 23510-L, 23520, 23520-L, 23540, 23557, 23804, 23810, 23810-L, 23811, 23811-L, 23814, 23820, 23820-L, 23821, 23821-L, 23824, 24222, 24224, 24330, 24610, 24612, 25020, 25020-L, 25021, 25035, 25070, 25082, 25090-BI, 25270, 25282, 25283, 25284, 25284-C, 25284-VSM, 25285, 25582, 25583, 25584, 25585, 26538, 52133, 52134, 52135, 52700, 20201F, 21111F, 21601F, 21701F, 21783-C, 22820-CLX, 22821-LILLY, 22840S, 25272-MS, 25272-MSL, 25274-MS, 25282-B, 25282-BC, 25282-C, 52423-U & 97206-MVPS.

Annex: VII

Classification: I

Classification: 5

Rules:

GMDN Code and 12849 – Otoscope, direct

**WelchAllyn®** **DECLARATION OF CONFORMITY**  
(in accordance with ISO/IEC 17050-1)

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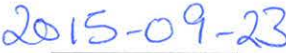
Term:


UMDNS Code and Term 12849 – Otoscopes

Standards Applied:	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN 1041	Information supplied by the manufacturer of medical devices
	EN/IEC 60601-1	Medical Electrical Equipment – General Guidelines for Safety
	EN/IEC 60601-1-2	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN/IEC 60601-1-6	Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability
	EN/IEC 62366	Medical Devices – Application of Usability Engineering to Medical Devices
	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Authorised Signatory:

  
\_\_\_\_\_  
Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

  
\_\_\_\_\_  
Date

  
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Place of Issue