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.
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	Otoscope
REF	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 Rules:	5
GMDN Code and	12849 – Otoscope, direct

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016526 Version: J

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 — 2015-09-23 — Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | Date | Place of Issue