Welch Allyn® DECLARATION OF CONFORMITY

SAP DIR No.: 80016526 Version: D

We declare, under our sole responsibility, that the product listed below conforms to the provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA
EC REP	Regulatory Affairs Representative Welch Allyn, Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	Otoscope
Model(s):	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, 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, 25270, 25282, 25283, 25284, 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 Rule:	5
GMDN Code and Term:	12849 – Otoscope, direct
UMDNS Code and Term	12849 – Otoscopes

Standards Applied:		
	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

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EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Authorised Signatory:

Fiona Butler	2013-10-08	Navan
Fiona Butler, Regulatory Affairs Representative	Date	Place of Issue