DECLARATION OF CONFORMITY

SAP DIR No.:	80016526	Version:	B

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 Ltd. Navan Business Park Dublin Road Navan, County Meath Republic of Ireland	
Product Name:	Otoscope	
Model(s):	20000, 20001, 20097, 20098, 20200, 20201, 20201F, 20202, 20203, 20250, 20251, 20260, 20261F, 20270, 20282, 20283, 20284, 20285, 21110, 21111, 21307, 21308, 21504, 21672, 21700, 21701, 21701F, 21770, 21782, 21783, 21783-C, 21784, 21785, 22009, 22091, 22100, 22800, 22160, 22811, 22812, 22820, 22821, 22822, 22831, 22840, 22841, 22860, 22861, 23100, 23101, 23101SM, 23102, 23104, 23106, 23510, 23520, 23557, 23804, 23810, 23820, 23824, 23842, 23860, 23862, 24222, 24224, 24610, 24612, 25020, 25021, 25035, 25070, 25082, 25270, 25274-MS, 25282, 25282-B, 25282-BC, 25282-C, 25283, 25284, 25285, 25582, 25583, 25584, 25585, 26531, 26535, 26538, 41100, 43300, 52401, 52423-U, 52700, 97206-MVPS, 700074, 700201, 700202	
Annex:	VII	
Classification:	I	
Classification Rule:	5	
GMDN Code and Term:	12849 – Otoscope, direct	
UMDNS Code and Term	12849 – Otoscopes	
Standards Applied:	ISO 14971	Medical devices - Application of risk management to medical devices
	IEC 60601-1	Medical Electrical Equipment – General Guidelines for Safety
	IEC 60601-1-2	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Authorised Signatory:

Kevin Crossen

Kevin Crossen, Regulatory Affairs Representative

2011-08-19

Date