Welch Allyn Declaration of Conformity

SAP DIR No.: 80017159 Version: A

We declare, und European Coun	ler our sole respon cil Directive 93/42	asibility, that the product listed below conforms to the provisions of 2/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:	Ophthalmoscopes		
Model(s):	11470, 11710, 11720, 11730, 11735, 11750, 11751, 11755, 11770, 11771, 11790, 11791, 11795, 11800, 11801, 11810, 11811, 11820, 11821, 11830, 11831, 11870, 11875, 12222, 12224, 12226, 12610, 12612, 12800, 12810, 12811, 12812, 12813, 12814, 12820, 12821, 12830, 12831, 12850, 12851, 12860, 12861, 13000, 13010, 14680, 14681, 19000, 19001, 19090, 19091, 19092, 19093, 19190, and 19192		
Annex:	VII		
Classification:	I		
Classification Rule:	12		
GMDN Code and Term:	12817 - Ophthalmoscope, direct		
UMDNS Code and Term	12817 - Ophthalmoscope, direct		
Standards Applied:	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	

Audiorisca Signatory:		2
Kevin Crossen, Regulatory Affairs Representative		D