Welch Allyn DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80019192 Version: D

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, USA
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	PanOptic Ophthalmoscope
REF	901022 OPHTHALMOSCOPE, WIDEVIEW
#	11800DEM, 11801, 11810, 11810-CE, 11810DEM, 11811, 11812-V, 11812-VSM, 11816-V, 11816-VC, 11816-VSM, 11820, 11820-CE, 11820-CEL, 11820DEM, 11820-L, 11821, 11821-L, 11822-V, 11822-VSM, 11824-V, 11824-VC, 11824-VSM, 11826-V, 11826-VC, 11826-VSM, 11870, 11875
Medical Device Conformity Assessment Route Annex:	VII
Medical Device Classification:	I
Medical Device Classification Rules:	12
GMDN Code and Term:	12817 - Ophthalmoscope, direct
UMDNS Code and Term	12817 - Ophthalmoscope, direct
Standards Applied:	EN/IEC 60601-1 Medical Electrical Equipment – General Guidelines for Safety

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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 15004-1	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 1: General Requirements Applicable to All Ophthalmic Instruments
EN/ISO 15004-2	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection
EN/ISO 10942	Ophthalmic Instruments - Direct Ophthalmoscopes
EN/ISO 10943	Ophthalmic Instruments - Indirect Ophthalmoscopes
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Authorised Signatory:

Fiona Butler — 2016-05-06 — Navan

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