Welch Allyn

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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[1,3]:	Ophthalmoscopes
REF [1,3]	901081, OPHTHALMOSCOPE, STANDARD 901082, OPHTHALMOSCOPE, POCKET
# [1,3]	11470F, 11710, 11710F, 11720, 11720F, 11720-L, 11720-LF, 11720R, 11721, 11721F, 11722, 11723, 11724, 11730, 11730F, 11730-R, 11731, 11732, 11735, 11735F, 11736, 11736F, 11750, 11750-VBI, 11770, 11770-BI, 11772-BI, 11772-VC, 11772-VCI, 11772-VCL, 11772-VSM, 11782-VSM, 11790, 11792-SC, 11796-SC, 12800, 12811, 12812, 12820, 12821, 12831, 12850, 12851, 12860, 12861, 12870-BLK, 12870-BLU, 12870-PUR, 12870-WHT, 12880-BLK, 12880-BLU, 12880-PUR, 12880-WHT, 13000, 13010, 19090, 19091, 19092, 19093, 19190
Radio equipment[2]:	Not applicable, no radio
Object of the declaration[2]:	Not applicable, no radio
Accessories and components[2]:	Not applicable, no radio
Medical Device Conformity Assessment Route Annex[1]:	VII
Medical Device Classification[1]:	I

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU

Medical Device Classification Rules[1]:	12	
GMDN Code and Term[1]:	46786 Direct ophthalmoscope, battery-powered	
UMDNS Code and Term[1]:	12817 – Ophthalmoscope, direct	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title
	EN 50581[3]	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	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 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/IEC 62471	Photobiological Safety of Lamps and Lamp Systems
	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Authorised Signatory:

Fiona Butler — 2018-04-30 — Navan

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

Date

Place of Issue

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU