

# Welch Allyn® DECLARATION OF CONFORMITY

SAP DIR No.: 80017159

Version: F

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: Ophthalmoscopes

**REF**

11470F, 11710, 11710F, 11720, 11720-L, 11720-LF, 11720R, 11730, 11730F, 11730-R, 11735, 11735F, 11736, 11750, 11750-VBI, 11751, 11770, 11770-BI, 11771, 11772-VCI, 11772-VCL, 11790, 11791, 11792-SC, 11796-SC, 11800ST, 11801, 11810, 11810-SPOT 11811, 11820, 11820-CEL, 11820-L, 11821, 11821-L, 11870, 11875, 12212-T, 12610, 12612, 12800, 12811, 12812, 12820, 12821, 12822, 12822, 12831, 12850, 12851, 12851, 12860, 12861, 13000, 13010, 19090, 19091, 19092, 19093, 19190.

Annex: VII

Classification: I

Classification Rule: 12

GMDN Code and UMDNS Code and Standards Applied: 12817 - Ophthalmoscope, direct

12817 - Ophthalmoscope, direct

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
EN/ISO 15004-1	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 1: General Requirements Applicable to All Ophthalmic Instruments

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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

Authorised Signatory:

  
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Fiona Butler, Regulatory Affairs Representative

2013-10-08  
Date

Navan  
Place of Issue