DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and
- 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, as amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 (RoHS3).

Document Number 80017159	Version W	
Product Name	Ophthalmoscope	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
Declaration of Conformity Validity	ISO 13485 #314505 MP2016 Expiry Date: 2022-12-08	
EC REP	Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland	SRN: IE-AR-000000768
Object of the declaration	 3.5V AutoStep Coaxial Ophthalmoscope  3.5V Coaxial Ophthalmoscope  3.5V Standard Ophthalmscope  Prestige Coaxial-Plus Ophthalmoscope  PocketScope Ophthalmoscope  **Pocket LED Ophthalmoscope**	

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Intended Purpose	The Ophthalmoscope is intended to be used to view the back of the eye, commonly called the fundus and is a useful diagnostic aid in studying other ocular structures.
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rules 1 & 10
Standards	Refer to Appendix A

REF #

901081: OPHTHALMOSCOPE, STANDARD
901082: OPHTHALMOSCOPE, POCKET

OPHTHALMOSCOPE, STANDARD

11710	11720-L	11721F	11735	11770	11772-VCL
11710F	11720-LF	11730	11735F	11772-BI	11772-VSM
11720	11720R	11730F	11750	11772-VC	
11720F	11721	11730-R	11750-VBI	11772-VCI	

OPHTHALMOSCOPE, POCKET

12800	12850	12870-BLK	12880-BLK	13000
12811	12851	12870-BLU	12880-BLU	13010
12820	12860	12870-PUR	12880-PUR	
12821	12861	12870-WHT	12880-WHT	

GMDN Code and Term	46788 Indirect monocular ophthalmoscope
UMDNS Code and Term	12818 Ophthalmoscope, indirect
Basic UDI-DI	0732094GMN901081F8 0732094GMN901082FA

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Approval

Joshua Kim, Sr. Manager, Global Regulatory Affairs	2021·12·22	Skaneateles Falls NY, USA
	Date	Place of Issue

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN 60601-1	2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN ISO 15004-2	2007	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection
	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 10993-1	2018	Biological evaluation of medical devices – Part 1: Evaluation and Testing
	EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in-vitro cytotoxicity
	EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
	EN 60601-1-2	2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
	EN 60601-1-6	2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
	EN 62366-1	2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
	EN ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	EN 62471	2008	Photobiological Safety of Lamps and Lamp Systems
Directive 2011/65/EU + (EU) 2015/863	EN IEC 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances