DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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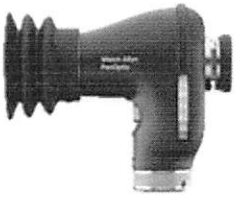
Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

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 80027950	Version J	
Product Name	Welch Allyn PanOptic Ophthalmoscopes	
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	 118-2  118-3	
Intended Purpose	The Welch Allyn PanOptic ophthalmoscopes are intended to be used by clinicians and medically qualified personnel for examination of the retina, cornea, aqueous, lens and vitreous of the eye under illumination and magnification on pediatric and adult patients.	
Medical Device Conformity Assessment Route Annex	Annex II and Annex III	
Medical Device Classification	Class I	
Medical Device Classification Rule	Rule 10	
Standards	Refer to Appendix A	

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REF #	901022: Ophthalmoscope, Wideview	
	118-2	118-3
GMDN Code and Term	46788 Indirect Monocular Ophthalmoscope	
UMDNS Code and Term	12818 Ophthalmoscope, Indirect	
Basic UDI-DI	0732094GMN901022EQ	

Accessories

Object of the declaration	**PanOptic Basic & Plus Eye Cup**  WA REF: *118-EC (PanOptic Basic & Plus Eye Cup, set of 5)*
Intended Purpose	The Welch Allyn PanOptic ophthalmoscopes are intended to be used by clinicians and medically qualified personnel for examination of the retina, cornea, aqueous, lens and vitreous of the eye under illumination and magnification on pediatric and adult patients.
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rule 1
Standards	Refer to Appendix A

REF #	901001: ACCESSORY, EYE, EAR, NOSE & THROAT 118-EC
GMDN Code and Term	46788 Indirect Monocular Ophthalmoscope
UMDNS Code and Term	12818 Ophthalmoscope, Indirect

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Basic UDI-DI	0732094GMN901001EG

Approval

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

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Appendix A: Standards and

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN ISO 10943	2011	Ophthalmic Instruments - Indirect Ophthalmoscopes
	EN ISO 15004-1	2020	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 1: General Requirements Applicable to All Ophthalmic Instruments
	EN ISO 15004-2	2007	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection
	EN 62471	2008	Photobiological Safety of Lamps and Lamp Systems
	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 10993-1	2010	Biological evaluation of medical devices – Part 1: Evaluation and Testing
	EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
	EN 60601-1-2	2014	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	2021	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 (ISO 15223-1:2016).
	EN 62471-2	2009	Photobiological Safety Of Lamps And Lamp Systems - Part 2: Guidance On Manufacturing Requirements Relating To Non-Laser Optical Radiation Safety

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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