DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Enhance Ophthalmoscopes
Document Number 80027950 Version: H

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

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- 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).

Product Name:	**Welch Allyn PanOptic Ophthalmoscopes**	
Manufacturer's Name and Address:	Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153 USA	SRN: None Issued
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road Navan, Co Meath, C15 AW22 Ireland	SRN: IE-AR-000000768
Conformity Assessment Route:	Annex II & Annex III, DoC per Article 19	
Technical Documentation:	DIR 60037080	
Part Numbers:	Refer to Appendix A for Part Numbers and their corresponding Class, Class Rule, GMDN Code, and UMDNS Code.	
Standards:	Refer to Appendix B	
Validity Limitation:	ISO 13485 #314505 MP2016 Expiry Date: 2022-12-08	

Welch Allyn, Inc. [a subsidiary of Hillrom, Inc.]
4341 State Street Road, Skaneateles Falls, NY 13153 USA
hillrom.com

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2021. 08. 24
Date

Skaneateles Falls NY ,
Place of Issue

Joshua Kim
Sr. Regulatory Compliance Mgr.

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Appendix A: Part Numbers

Device

Class:	I	
Class Rule:	10	
GMDN Code and Term:	46788	**Indirect Monocular Ophthalmoscope**
UMDNS Code and Term:	12818	**Ophthalmoscope, Indirect**

Basic UDI/DI: 0732094GMN901022EQ

REF	#	Description
118-2, 118-3	901022	Ophthalmoscope, Wideview

Accessories

Class:	I	
Class Rule:	1	
GMDN Code and Term:	46788	Indirect Monocular Ophthalmoscope
UMDNS Code and Term	12818	Ophthalmoscope, Indirect

Basic UDI/DI: 0732094GMN901001EG

REF	#	Description
118-EC	901001	ACCESSORY, EYE, EAR, NOSE & THROAT

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Appendix B: Standards (and Common Specifications)

Number	Title
:N 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
:N ISO 10942	Ophthalmic Instruments - Direct Ophthalmoscopes
:N ISO 15004-1	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 1: General Requirements Applicable to All Ophthalmic Instruments
:N ISO 15004-2	Ophthalmic Instruments – Fundamental Requirements and Test Methods – Part 2: Light Hazard Protection
:N 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
EN 63000	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
:N 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
:N 62471	Photobiological Safety of Lamps and Lamp Systems
:N ISO 15223-1	Medical Devices - Symbols to be Used with medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements
:N ISO 14971	Medical Devices - Application of Risk Management to Medical Devices
:N ISO 13485	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
:N 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
:N ISO 10993-1	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process

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Document Change History

Version	Description	Author	Date
A	Initial Release	C. Lefancheck	02/16/2021
B	Added GMDN codes and updated manufacturer address	C. Lefancheck	03/19/2021
C	EUMDR updates	C. Lefancheck	05/12/2021
D	Updates to translations	C. Lefancheck	05/26/2021
E	Updates to translated signatures	C. Lefancheck	06/15/2021
F	Updated for RoHS 3	K Ockenfels	07/20/2021
G	Updated for RoHS3, added SRN, added Rev table.	K Ockenfels	08/04/2021
H	EU MDR Updates, Updated SAP Change Number	K. Love	08/23/2021

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