DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Document Number: 80027949 **Version: J**

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:	**Otoscope**	
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 60037632	
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	

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Authorised Signatory:

Joshua Kim
Sr. Regulatory Compliance Manager

2021. 08. 24
Date

Skaneateles Falls, NY
Place of Issue

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Appendix A: Part Numbers

Device

Class:	I	
Class Rule:	5, 10	
GMDN Code and Term:	12849	Otoscopes, Direct
UMDNS Code and Term	12849	Otoscopes
Basic UDI/DI:	0732094GMN901021EN	

REF	#	Description
238-2, 238-3, 250-2	901021	Otoscope, Wideview

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Appendix B: Standards (and Common Specifications)

Number	Title
EN ISO 13485	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices
EN 63000	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
EN 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 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
EN 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
EN ISO 10993-1	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
EN/ISO 15223-1	Medical Devices - Symbols to be Used with medical Device Label, Labelling and Information to be Supplied - Part 1: General Requirements
EN 62471	Photobiological Safety of Lamps and Lamp Systems

Document Change History

Welch Allyn, Inc.
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Version	Description	Author	Date
A	Initial Release	C. Lefancheck	02/16/2021
B	Update to Manufacturer Address	C. Lefancheck	03/19/2021
C	Updated GMDN and UMDNS	C. Lefancheck	03/24/2021
D	Correction of UMDNS Code	C. Lefancheck	04/07/2021
E	Updated for EUMDR	C. Lefancheck	05/12/2021
F	Updated for EUMDR	C. Lefancheck	06/15/2021
G	Updated for RoHS3	K Ockenfels	07/20/2021
H	Updated for RoHS 3, added SRN Number, added missing rule 10.	K Ockenfels	08/16/2021
J	Remove: EN ISO780, ISO7000, EN1041 from English, and ISO10993-5 & -10, ENIEC 62281, EN61951-1, EN62133-1 & -2 from translations	Scott Stearns	08/23/2021

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