DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Enhance Otoscopes
Document Number 80027949 Version: D

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

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the 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 (RoHS)

Product Name:	**Otoscope**
Manufacturer's Name and Address:	Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153 USA
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road, Navan, Co Meath, C15 AW22, Ireland
Conformity Assessment Route:	Annex VII
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
Declaration of Conformity Validity:	This manufacturer's declaration of conformity is valid from the date of issue and remains valid until it is superseded or withdrawn due to product change or expiry of the QMS certificate.
QMS Certificate Number:	314505 MP2016
QMS Certificate Validity:	Expiry date: 2022-12-08

Joshua Kim — 2021-04-07 — Skaneateles Falls NY, USA

Joshua Kim
Senior Regulatory Affairs Manager

Date

Place of Issue

Welch Allyn, Inc.
4341 State Street Road, Skaneateles Falls, NY 13153 USA
hillrom.com

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Appendix A: Part Numbers

Device

Class	I
ClassRule	5
GMDN Code and Term:	12849 Otoscopes, Direct
UMDNS Code and Term:	12849 Otoscopes

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

Accessory

Class	I
ClassRule	5
GMDN Code and Term:	34897 Ear Speculum, Single-Use
UMDNS Code and Term:	13662 Specula, Aural

#	REF	Description
901001	52432-CLR-1, 52434-CLR-1, 52432-CLR-2, 52434-CLR-2	Accessory, Eye, Ear, Nose & Throat

Appendix B: Standards (and Common Specifications)

Number	Title
EN ISO 780	Packaging -- Pictorial marking for handling of goods
ISO 7000	Graphical Symbols for Use on Equipment - Registered Symbols
EN ISO 13485	Medical Devices - Quality Management Sysystems - Requirements for Regulatory Purposes
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices
EN 50581	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

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EN 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
EN 1041	Information Supplied by the Manufacturer of 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 Labesl, Labelling and Information to be Supplied - Part 1: General Requirements
EN 62471	Photobiological Safety of Lamps and Lamp Systems

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