



# 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 80027949

Version M

Product Name

Otoscope

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: 2024-11-07

**EC REP**

Welch Allyn Limited,  
Navan Business Park, Dublin Road,  
Navan, Co. Meath, C15 AW22  
Ireland

SRN: IE-AR-000000768

Object of the declaration



Intended Purpose

The Welch Allyn MacroView and LED otoscopes are intended to be used by clinicians and medically qualified personnel for examination of the external ear, ear canal, and tympanic membrane under illumination and magnification on pediatric and adult patients. The otoscope is also intended to assess the flexibility of the tympanic membrane through air pressure and for general illumination of the oral and nasal cavities.

Medical Device Conformity Assessment Route Annex

Annex II and Annex III

Medical Device Classification

Class I

Medical Device Classification Rule

Rules 5, 10

Standards

Refer to Appendix A

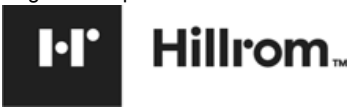


# DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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

<b>REF</b> <b>#</b>	901021: Otoscope, Wideview
	238-2
	238-3
	250-2
GMDN Code and Term	12849 Otoscopes, Direct
UMDNS Code and Term	12849 Otoscopes
Basic UDI-DI	0732094GMN901021EN



# DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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

## Approval

DocuSigned by Jeffrey E. Thompson



I approve this document  
13-Jan-2023 | 13:32:51 CST

B72D35F2F6884440B72DE91619D05869

13-Jan-2023 | 13:35:09 CST

Jeffrey E Thompson, Manager, Regulatory Affairs	Date	Skaneateles Falls, NY USA Place of Issue
---	------	--



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

### Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN 62471-2	2009	Photobiological Safety Of Lamps And Lamp Systems - Part 2: Guidance On Manufacturing Requirements Relating To Non-Laser Optical Radiation Safety
	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN 62471	2008	Photobiological Safety of Lamps and Lamp Systems
	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 ISO 14971	2019	Medical devices-Application of risk management to medical devices
	EN 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	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 ISO 20417	2021	Medical devices – Information to be supplied by the manufacturer
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

**DECLARATION OF CONFORMITY**

(in accordance with ISO/IEC 17050-1)

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

## Document Change History

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
K	Updated to new template, added Intended Purpose Statement, updated standards list per Enhance ASL.	K Ockenfels	11/11/2021
L	Updated standards list to include EN ISO 14971:2019 and EN ISO 20417:2021.	K Ockenfels	04/12/2022
M	Updated DOC ISO 13485 Expiration date	M Solanki	12/06/2022