# 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.<br>4341 State Street Road<br>Skaneateles Falls, NY 13153<br>USA | SRN: US-MF-000013394 |
| Declaration of Conformity Validity | ISO 13485 #314505 MP2016 Expiry Date: 2024-11-07 | |
| EC REP | Welch Allyn Limited,<br>Navan Business Park, Dublin Road,<br>Navan, Co. Meath, C15 AW22<br>Ireland | SRN: IE-AR-000000768 |
| Object of the declaration |  250-2  238-2  238-3 | |
| 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 | |

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

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**Approval**

DocuSigned by Jeffrey E. Thompson

Jeffrey E. Thompson | I approve this document 13-Jan-2023 | 13:32:51 CST

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

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

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**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 |

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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 |