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 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).

Document Number 80016526	Version Z
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: 2022-12-08
EC REP	Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland SRN: IE-AR-000000768
Object of the declaration	 Macroview  Diagnostic  Pneumatic  Operating
Intended Purpose	Welch Allyn Otoscopes are hand-held, battery-powered devices that are intended to be used by trained clinicians during a patient health assessment to inspect the external ear, ear canal and tympanic membrane under illumination and magnification. Secondary uses of the Otoscopes are to provide general illumination of the throat and/or nasal cavities. The Welch Allyn Pocket LED Otoscope and associated accessories are intended to illuminate and visualize the ear canal and tympanic membrane to assess the health of the ear and support diagnoses of conditions of the ear.
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I

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Medical Device Classification Rule	Rule 5

REF #

901021: Otoscope Wideview
901079: Otoscope, Standard
901080: Otoscope Pocket

Otoscope Wideview

23810	23810-L
23820	23820-L
23811	23811-L
23821	23821-L

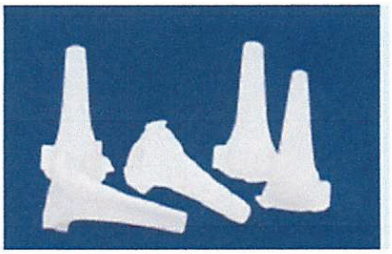
Otoscope Standard

20000	20000-L	20200	20201	20250
20270	20283	20285	21700	21701
21770	21785	23510	23510-L	23520
23520-L	25020	25020-L	25021	25035
25070	25082	25090-BI	25270	25282
25284	25284-C	25284- VSM	25584	20201F
25582	21701F	25272-MS	25272- MSL	25274-MS
25282-C	25282-VSM			

Otoscope Pocket

21111	21140	21141	22100	22800
22811	22820	22821	22822	22840
22841	22860	22861	22870- BLK	22870- BLU
22870-PUR	22870- WHT	22880- BLK	22880- BLU	22880- PUR
22880- WHT	21111F	22820-CLX		

GMDN Code and Term	12849 Otoscope, direct
UMDNS Code and Term	12849 Otoscopes
Basic UDI-DI	0732094GMN901021EN 0732094GMN901079FM 0732094GMN901080F6

Standards	Refer to Appendix A
Object of the declaration	Accessories  
Intended Purpose	The Disposable Tips are intended to be used as an accessory with the Welch Allyn Otoscopes (the 238 and the 235 series). The device allows examination of the ear via insertion of the tip into the ear canal in order to hold open the outermost portion or the cartilaginous meatus and to aid the transmission of the light from the Otoscope down the canal to the tympanic membrane. The disposable tip is intended for a one-time use. The Reusable Tips are intended to be used as an accessory with the Welch Allyn Otoscopes (the 238 and the 235 series). The device allows examination of the ear via insertion of the tip into the ear canal in order to hold open the outermost portion of the cartilaginous meatus and to aid the transmission of the light from the Otoscope down the canal to the tympanic membrane. The reusable tip is intended for multiple use and to be cleaned after each use. The Instrumentation Tips are intended to be used as accessories with the Welch Allyn 238 Otoscope series. The device allows removal of cerumen from the external ear canal. The disposable instrumentation tip is intended for a one-time use. The sealing tips are intended to be used as accessories with the Welch Allyn 235, and 238 Otoscope series This device allows to sufficiently seal the ear to perform pneumatic otoscopy
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rule 5

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901001 Accessory, EYE, EAR, NOSE and THROAT

REF #

21501	21504	22009	23540	23804
23824	52133	52133-B	52134	52134-B
52135	52135-B	52700	24302-U	24303-U
24304-U	24305-U	24320	24320-B	24330
24330-B	24400-U	52432-U	52434-U	52700
52432-UB	52434-UB	24323	24325	24327
24420	52432-CLR-1	52434-CLR-1	22002	22003
22004	22005	22023	22025	22027
22120	52432-CLR-2	52434- CLR-2		

GMDN Code and Term	34897 Ear Speculum, Single Use 33395 Ear Speculum, Reusable
UMDNS Code and Term	13662 Specula, Aural
Basic UDI-DI	0732094GMN901001EG
Standards	Refer to Appendix A

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Approval

Joshua Kim, Sr. Manager, Global Regulatory Affairs	2022 · 01 · 31	Skaneateles Falls, NY USA
	Date	Place of Issue

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN ISO 10993-10	2013	Biological evaluation of medical devices_- Part_10: Tests for irritation and skin sensitization
	EN ISO 10993-1	2018	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
	EN ISO 10993-5	2009	Biological evaluation of medical devices_- Part_5: Tests for in vitro cytotoxicity
	EN 60601-1	2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2	2015	Medical electrical equipment_- Part_1-2: General requirements for basic safety and essential performance_- Collateral standard: Electromagnetic compatibility_- Requirements and tests
	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
	EN 60601-1-6	2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
	EN ISO 13485	2016	Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes
	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
	EN 62366-1	2015	Medical devices_- Application of usability engineering to medical devices
	EN 62471	2008	Photobiological Safety of Lamps and Lamp Systems
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