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 dev ices
- 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: AB
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	 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	
GMDN Code and Term	12849 Otoscope, direct	

UMDNS Code and Term	12849 Otoscopes
Basic UDI-DI	0732094GMN901021EN 0732094GMN901079FM 0732094GMN901080F6
Standards	Refer to Appendix A

Otoscope Wideview	
23810	DIAG OTOSCOPE
23810-L	DIAG OTOSCOPE W/LED
23811	Diag Otoscope
23811-L	DIAG OTOSCOPE - LED
23820	Diag Otoscope with Throat Illuminator
23820-L	DIAG OTOSCOPE W/THROAT ILLUM & LED
23821	Diag Otoscope with Throat Illuminator
23821-L	DIAG OTOSCOPE W/THROAT ILLUM & LED
Standard Otoscope	
20000	3.5V HAL DIAG OTO/THROAT ILLUM
20000-L	3.5V DIAG OTO W/THROAT ILLUM & LED
20200	3.5V HAL PNEUMATIC OTOSCOPE
20201	3.5V HAL PNEU OTO W/O SPECS
20201F	3.5V HAL PNEU OTO W/O SPECS
20250	3.5V OTO-12 DIOPTER LENS
20270	3.5V HAL OTOSCOPE SET
20283	3.5V HAL OTOSCOPE SET - IEC
20285	3.5V HAL OTOSCOPE SET - IEC
21700	3.5V HALOGN OPERATING OTOSCOPE
21701	3.5V HAL OPER OTOS W/O SPECS
21701F	3.5V HAL OPER OTOS W/O SPECS
21770	3.5V HALOGN OPER OTOSCOPE SET
21785	HAL OPER OTO
23510	3.5V OTOSCOPE
23510-L	3.5V OTOSCOPE - LED
23520	3.5V DIAG OTO W/THRT ILLUM
23520-L	3.5V DIAG OTO W/THRT ILLUM -LED
25020	3.5V HAL DIAG OTOSCOPE
25020-L	3.5V DIAG OTOSCOPE W/LED
25021	3.5V HAL DIAG OTO W/INSUFF
25035	3.5V HAL DIAG OTOSCP W/O SPECS
25070	3.5V HALOGEN OTOSCOPE SET
25082	HAL OTO
25090-BI	3.5V HALOGEN OTOSCOPE SET
25270	3.5V HALOGEN OTOSCOPE SET
25272-MS	PRESTIGE OTOSCOPE SET - EUR
25272-MSL	PRESTIGE OTOSCOPE SET W/LED - EUR

25274-MS	PRESTIGE OTOSCOPE SET - UK
25282	HAL OTO SET
25282-C	3.5V HALOGEN OTOSCOPE SET, IEC
25282-VSM	HAL OTO SET, CE
25284	HAL OTO
25284-C	3.5V HALOGEN OTOSCOPE SET-IEC
25284-VSM	HAL OTO SET CE
25582	OTOSCOPE SET - IEC
25584	OTOSCOPE SET - IEC
Otoscope Pocket	
21111	POCKETSCOPE OTOSCOPE
21111F	POCKETSCOPE OTOSCOPE
21140	POCKET JR OTOSCOPE BOXED
21141	POCKET JR OTOSCOPE
22100	SET OF 5 POLY SPECULA
22800	POCKETSCOPE OTOSCOPE/RECHG HDL
22811	POCKETSCOPE OTOS/RECHG HDL/CS
22820	POCKETSCOPE OTOS/AA HDL
22820-CLX	POCKETSCOPE OTOS/AA HDL
22821	POCKETSCP OTO/AA HDL/SOFT CS
22822	POCKETSCP OTO/AA HDL/HARD CS
22840	POCKET JR OTOSCOPE & HANDLE
22841	POCKET JR OTO, HANDLE, CASE
22860	KLINIC POCKETSET OTO ST W/HNDL
22861	KLINIC POCKETSET OTO SET
22870-BLK	POCKET LED OTOSCOPE/ONYX W/ HANDLE
22870-BLU	POCKET LED OTOSCOPE/BLUEBERRY W/ HANDLE
22870-PUR	POCKET LED OTOSCOPE/PLUM W/ HANDLE
22870-WHT	POCKET LED OTOSCOPE/VANILLA W/ HANDLE
22880-BLK	POCKET PLUS LED OTO/ONYX W/ HANDLE
22880-BLU	POCKET PLUS LED OTO/BLUEBERRY W/ HANDLE
22880-PUR	POCKET PLUS LED OTO/PLUM W/ HANDLE
22880-WHT	POCKET PLUS LED OTO/VANILLA W/ HANDLE

Accessories

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Object of the declaration	 
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
GMDN Code and Term	34897 Ear Speculum, Single Use 33395 Ear Speculum, Reusable
UMDNS Code and Term	13662 Specula, Aural
Basic UDI-DI	0732094GMN901001EG 0732094GMN901021EN
Standards	Refer to Appendix A

REF #

901001 Accessory, EYE, EAR, NOSE and THROAT	
21501	OTOSCOPE INSUFFLATION BULB
21504	OTOSCOPE INSUFFLATION BULB/TIP
22002	POLY SPECULUM 2MM
22003	POLY SPECULUM 3MM
22004	POLY SPECULUM 4MM
22005	POLY SPECULUM 5MM
22009	POLY SPECULUM 9MM
22023	SPFSPEC OTOSCOPE SPECULUM. 3MM
22025	SOFSPEC OTOSCOPE SPECULUM. 5MM
22027	SOFSPEC OTOSCOPE SPECULUM. 7MM
22120	SET OF 3 SOFSPEC SPECULA
23804	OTOSCOPE INSUFFLATION BULB/TIP
23824	OTOSCOPE INSUFFLATION BULB
24320	SOFSEAL - 1CASE - SMALL
24323	SOFSPEC OTOSCOPE SPECULUM.3MM
24325	SOFSPEC OTOSCOPE SPECULUM. 5MM
24327	SOFSPEC OTOSCOPE SPECULUM. 7MM
24330	SOFSEAL - 1CASE - MEDIUM
24420	SET OF 3 SOFSPEC SPECULA
52133	KLEENSPEC OTOSCOPE SPEC. 3MM
52134	KLEENSPEC OTOSCOPE SPEC, 4MM
52135	5MM DISPOSABLE SPECULA
52700	13STRUMENTATION TIP -1 CASE
24304-U	UNIVERSAL POLY SPECULUM 4MM
24320-B	SOFSEAL - 1 BOX - SMALL
24330-B	SOFSEAL - 1 BOX - MEDIUM
24400-U	POLY SPECULA SET OF 4
52133-B	KLEENSPEC OTOSCOPE SPEC 3MM
52134-B	KLEENSPEC OTOSCOPE SPEC 4MM
52135-B	KLEENSPEC OTOSCOPE SPEC 5MM
52432-CLR-1	2.75MM EAR SPECULA 20 SLEEVES OF 34 TIPS
52432-CLR-2	2.75MM EAR SPECULA (CASE OF 10 BAGS)
52432-U	2.75mm UNIVERSAL SINGLE USE PED TIP CASE
52432-UB	2.75MM UNIVERSAL DISP PED TIPS - BOX 850
52432-UB	2.75MM UNIVERSAL DISP PED TIPS - BOX 850
52434-CLR-1	4.25MM EAR SPECULA 20 SLEEVES OF 34 TIPS
52434-CLR-2	4.25MM EAR SPECULA (CASE OF 10 BAGS)
52434-U	4.25mm UNIVERSAL SNGLE USE ADLT TIP CASE
52434-UB	4.25MM UNIVERSAL DISP ADLT TIPS - BOX850

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Approval

Signature: Jeffrey Thompson

Electronically signed by: Jeffrey Thompson
Reason: I approve this document
Date: Mar 25, 2024 13:15 CDT

Email: jeffrey_thompson@baxter.com

Jeff Thompson Manager, Regulatory Affairs	Date	Skaneateles Falls, NY USA Place of Issue

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN ISO 10993-10	2021	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	2021	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

Document Change History

Version	Description	Author	Date
A	Initial SAP release	Gary Brennan	2010/10/08
B	Update to the new DoC format	Gary Brennan	2010/10/20

C	Update to DoC Version Rev 5	Gary Brennan	2011/04/29
D	Removed OB and SO materials	Paul Oris	2014-04-03
E	Added Annex	Paul Oris	2014-04-17
F	Added RoHS compliance	Paul Oris	2014-07-14
G	Added RPI-REF; added Pocket LED catalog numbers Updated Standards to add 62366 & 10993-1	Megan Pellenz	2014-11-03
H	Updated DoC to include REF 901021, OTOSCOPE, WIDEVIEW	M. McGovern	2015-08-24
J	Added missing parts: 25090-BI, 25284-C, and 25284-VSM (Shipping label contains CE mark, Otoscopes are included on the RoHS Compliance statement, 30045371) Updated Annex to include all part listed in main DoC.	S. Schmidt	2015-09-17
K	Updated DoC to include REF 901001 ACCESSORY EYE, EAR NOSE AND THROAT. Added missing parts 21501, 24320, 24323, 24325, 24327, 24220. Deleted 97206-MVPS (it is a "kit"), 23557 (ACCESSORY / COMPONENT) and obsolete parts 20001, 20097, 20098, 20203, 21307, 21308, 21783, 22091, 24222, 24224, 24610, 24612, 25283, 25285, 25583, 25585, 21783-C, 22821-LILLY, 22840S, 25282-BC, 52423-U. Deleted 26538 as it is already showing on the Illuminator and Transilluminator DoC.	M. McGovern	2018-05-09
L	Added missing part 24420 Deleted 24320, 24330; these parts are already showing on a separate DoC	M. McGovern	2018-10-10
M	Added missing part 25282-VSM	M. McGovern	2019-06-21
N	Add new ClearSpec p/n's 52432-CLR-1, 52434-CLR-1, 52432-CLR-2, 52434-CLR-2	Scott Stearns	2020-06-04
P	HCL Redlines for EUMDR	RAJUS1	2020-09-27
R	Updated for EUMDR	C. Lefancheck	2021-05-27
S	Updated for EUMDR additional content	C. Lefancheck	2021-06-16
T	Updated for RoHS3	K Ockenfels	2021-07-22

U	Updated for RoHS3, added SRN, added Rev table. . Deleted p/n's : 20251, 20282, 20284, 22831, 25282-B (OB) - 21601F, 21110 (RO); 24220 (NQ); 21782, 21784 (DC). Removed EN ISO 10993-5 and 10993-10.	K Ockenfels S.Co	2021-08-18
W	Deleted battery standards, deleted EN 1041	K. Love	2021-08-25
X	Not used.		
Y	Transfer to new format. Add Intended Purpose statement.	K. Love/S. Co	2021-11-05
Z	Updated Typo 54434-CLR-1 to correct part number 52434-CLR-1	K Ockenfels	2022-01-25
AA	Updated DOC ISO 13485 Expiration date	M Solanki	2022-12-06
AB	Updated the Product description against each SKU	A. Yellina	2024-03-19