Hillrom™

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DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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	80016490	Version T
Product Name	Retinoscope	
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	 3.5V Elite Streak Ret. Gold	
Intended Purpose	A Retinoscope is an AC-powered or battery-powered device intended to help measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.	
Medical Device Conformity Assessment Route Annex	Annex II and Annex III	

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Medical Device Classification	Class I
Medical Device Classification Rule	Rule 10
Standards	Refer to Appendix A
REF #	901024: Retinoscope 18240 — 3.5V ELITE STREAK RET. (WHITE) 18245 — 3.5V ELITE STREAK RET. GOLD 18300 — 3.5V SPOT RETINOSCOPE
GMDN Code and Term	32712 Retinoscope, battery-powered
UMDNS Code and Term	13372 Retinoscopes
Basic UDI-DI	0732094GMN901024EU

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Approval

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 60601-1	2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	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 15004-1	2009	Ophthalmic instruments_- Fundamental requirements and test methods_- Part_1: General requirements applicable to all ophthalmic instruments
	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
	EN ISO 10993-1	2018	Biological evaluation of medical devices – Part 1: Evaluation and Testing.
	EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in-vitro cytotoxicity
	EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
	EN 60601-1-2	2015	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	2015	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	2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
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	Updated from DOC-MDD-069 Rev 3	K. Davis	2010-10-29
B	Revised to form version 5 and correct certificate references	P. Oris	2011-09-18
C	Removed parts that are no longer sold. Updated format to support Saudi submission. Note: RPI is on label so annex is not needed.	S. Schmidt	2014-04-21
D	Added 18210-BI since it only contains a retinoscope (not a kit) and is CE marked.	S. Schmidt	2014-06-26
E	Adding RoHS Doc elements	S. Schmidt	2014-07-01
F	Updated GMDN Code	M. McGovern	2015-08-28
G	Added 18342-VC since it contains a retinoscope and power handle (it is not a kit) and is CE Marked.	M. McGovern	2015-12-23
H	Updated to the current version of the template. Deleted 18210-BI as it is now OB.	B. Rice	2019-02-21
J	Added 18344-V. Added reference to location of translated version on document change history tab.	B Rice	2019-07-11
K	Updated for EUMDR	C. Lefancheck	2021-05-27
L	Updated for additional EUMDR information	C. Lefancheck	2021-06-16
M	Updated for RoHS 3	K Ockenfels	2021-07-22
N	Updated for RoHS, added SRN, added Rev table	K. Ockenfels	2021-08-18
P	Correction and EN62353 removed from translation	Scott Stearns	2021-8-23
Q	Not Used		
R	Transfer to new format. Add Intended Purpose statement. Break out 10993-5 and 10993-10.	K. Love/S. Co	2021-11-05
S	Updated DOC ISO 13485 Expiration date	M Solanki	2022-12-06
T	Updated the Product description against each SKU	A. Yellina	2024-03-19