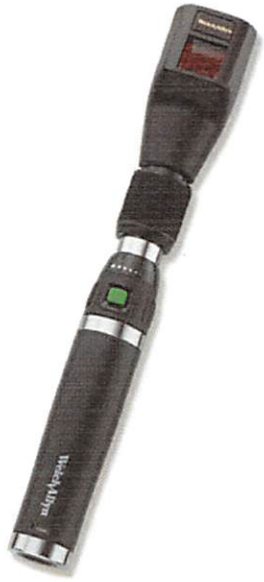
DECLARATION OF CONFORMITY

(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 80016490	Version R	
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: 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	 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.	

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

Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rule 10
Standards	Refer to Appendix A

REF #	901024: Retinoscope		
	18240	18300	18344-V
	18245	18342-VC	
GMDN Code and Term	32712 Retinoscope, battery-powered		
UMDNS Code and Term	13372 Retinoscopes		
Basic UDI-DI	0732094GMN901024EU		

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

Approval

Joshua Kim, Senior Manager, Global Regulatory Affairs	2021.12.22	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 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	2016	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