EU Declaration of Conformity (DoC)

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

EU DoC ID	*80016490 Rev U*

Manufacturer Name and Address: Welch Allyn, Inc.

4341 State Street Road

Skaneateles Falls, NY 13153, USA

Manufacturer Single Registration Number (SRN): US-MF-000013394

Authorised Representative Name and Address: Welch Allyn Limited,

Navan Business Park, Dublin Road,

Navan, Co. Meath, C15 AW22

Ireland

Authorised Representative Single Registration Number (SRN): IE-AR-000000768

+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++

Other relevant Directives, Regulations and Union Legislations that the device is in conformity with: N/A

Common Specifications Applied: N/A

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Product/Trade Name and Product Code or REF. number:

901024: Retinoscope

18240	3.5V ELITE STREAK RET. (WHITE)
18245	3.5V ELITE STREAK RET. GOLD
18300	3.5V SPOT RETINOSCOPE

Intended Purpose/Use: 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.

Device Risk Class: Class I

Product Basic UDI-DI Number: 0732094GMN901024EU

MDR EU Certificate(s) No.: N/A

Conformity Assessment Description/Annexes: Annex II and Annex III Rule 10

Notified Body Name and Address: N/A

Notified Body Identification Number: N/A

+++ This Declaration is made on the following basis:

- For devices with a MDR EU Certificate issued by a Notified Body:
  - The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.
  - The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.
- For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature.
- Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
- Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Authorised Signatory:	
Name and Title:	Joseph Olsavsky, Sr. Director Regulatory Affairs

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Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA
Date of Issue:	November 13, 2024
Signature:	JOSEPH OLSAVSKY *Electronically signed by:* *JOSEPH OLSAVSKY* *Reason: I approve this document* *Date: Nov 18, 2024 08:22 EST*