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 W

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

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

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

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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
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA
Date of Issue:	September 03, 2025
Signature:	

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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
U	Updated Hill-Rom to Baxter DoC Template	M Solanki	2024-11-18
W	Removed Product Code 18300 as it is EOL.	B. Cook	2025-09-03