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We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- European Council Directive 93/42/EEC of 14 June 1993 concerning 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 80016451 Version H

Product Name EpiScope Skin Surface Microscope

 Manufacturer's Name and Business Address Welch Allyn, Inc. SRN: None issued
 4341 State Street Road
 Skaneateles Falls, NY 13153
 USA

Declaration of Conformity Validity EC Certificate 314505 MR2 Expiry Date: 2024-05-26

EC Certificates EC Certificate 314505 MR2


 and Importer

 Welch Allyn Limited
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SRN: IE-AR-000000768



47300,47310,47320, 47351, 47352, 47352-C, 47354, 47351-SM, 47352-BI, 47352-SM, 47354-SM, 47356-SM, 47357-SM, 47301, 47356, 47351-C, 47354-C

 Radio equipment 901068 – Skin Surface Microscope
 N/A

Object of the declaration



EpiScope Skin Surface Microscope

Accessories and components See Appendix A

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Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	I(m)
Medical Device Classification Rule	12
Standards	See Appendix B
GMDN Code and Term	18201: Dermatoscope, optical
UMDNS Code and Term	12536 - Microscopes
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

Authorised Signatory


Joshua Kim
Senior Manager
Global Regulatory Affairs

2021.09.13
Date

Skaneateles Falls NY, USA
Place of Issue



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Appendix A: Accessories and Components

SKU	Description
N/A	No Accessories

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Appendix B: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN60601-1-2	2014	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
	60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard
	EN 62366-1	2015	Medical devices -- Part 1: Application of usability engineering to medical devices
	EN ISO 10993-1	2010	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
Directive 2011/65/EU + (EU) 2015/863	EN 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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Document Change History

Version	Description	Author	Date
A	Update classification to Class 1 Measuring. Update to the new DoC format Reference DoC EpiScope 2010/04/09	Gary Brennan	2012-10-05
B	Revised to used form version 5 and update certificate references	J Frasier	2011-10-10
C	<ul style="list-style-type: none"> • Added 47351-SM, 47352-BI, 47352-SM, 47354-SM, 47356-SM, 47357-SM, 47301, 47356, 47351-C, 47354-C (previously omitted). • Removed 47370 (Obsolete part). • Update document template to Rev 7. <p>Changed Annex from VII to II.</p>	G. Brennan	2013-05-03
D	Old EC Cert number was referenced, Changed to 314505 MR2	F. Butler	2014-02-20
E	Update to new format to add RoHS	L. Bernardoni	2014-07-17
F	Updated to newest template (DIR 80019151 Ver. C) Removed GMDN Code and description (35484 - Microscope, light) Added new GMDN code and description (18021 Dermatoscope, optical)	K. Sacco	2015-11-09
G	Updated DoC to new format	B. Rice	2019-07-15
H	Updated to new Hillrom Template. Verified standards, updated RoHS 3 statement.	K. Ockenfels	2021-09-08