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:

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the 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 (RoHS)

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name[1,3]:	EpiScope Skin Surface Microscope
REF [1,3]	901068 – Skin Surface Microscope
# [1,3]	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[2]:	Not Applicable
Object of the declaration[2]:	Not Applicable
Accessories and components[2]:	Not Applicable
Medical Device Conformity Assessment Route Annex[1]:	II
Medical Device Classification[1]:	I(m)
Medical Device Classification Rules[1]:	12
GMDN Code and Term[1]:	18021 - Dermatoscope, optical

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU

UMDNS Code and Term[1]:	12536 - Microscopes
Notified Body[1]: (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2.

Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title
	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN60601-1:	Medical Electrical Equipment, Part 1: General Requirements for Safety.
	EN60601-1-2	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
	EN 62366	Medical devices - Application of usability engineering to medical devices

Authorised Signatory:

Fiona Butler

2019-07-29

Navan

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

Date

Place of Issue

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU