

# Welch Allyn® DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016451 Version: F

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: EpiScope Skin Surface Microscope

**REF**

901068 SKIN SURFACE MICROSCOPE

**#**

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

Medical Device Conformity Assessment Route Annex: II

Medical Device Classification: I(m)

Medical Device Classification Rules: 12

GMDN Code and Term: 18021 Dermatoscope, optical

UMDNS Code and Term: 12536 Microscopes

Notified Body: (CE 0297) DQS Medizinprodukte GmbH,  
August-Schanz-Str.21, 60433 Frankfurt am Main  
EC-certificate No. 314505 MR2

Standards Applied: EN 50581 Technical documentation for the assessment of electrical and electronic products with respect to the



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EN ISO 14971

restriction of hazardous substances

Medical Devices - Application of Risk Management  
to Medical Devices

Authorised Signatory:

\_\_\_\_\_  
Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

2016-06-17

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Date

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Place of Issue