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 13153-0220 U.S.A
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name[1,3]:	KleenSpec® Vaginal Specula
REF [1,3]	901071 VAGINAL SPECULUM
# [1,3]	58600, 59000, 59001, 59004, 59005, 59006, 58000S, 58001S, 58004S, 59000-B, 59001-B, 59004-B, 590XS, 590XS-B
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]:	VII
Medical Device Classification[1]:	I
Medical Device Classification Rules[1]:	5 and 12
GMDN Code and	37468 Vaginal Speculum, single use

[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

Term[1]:		
UMDNS Code and Term[1]:	13666 Speculum, Vaginal	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
	IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility
	IEC 62366	Medical devices – Application of usability engineering to medical devices
	IEC 60601-1-6	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	EN ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2018-12-10
Date

Navan
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