DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

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

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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 80016468	Version P	
Product Name	KleenSpec® Vaginal Specula Illumination System	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
Declaration of Conformity Validity	ISO 13485 #314505 MP2016 Expiry Date: 2022-12-08	
EC REP	Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland	SRN: IE-AR-000000768
Object of the declaration		
	Kleenspec® Single Use 590 Series LED Vaginal Specula	
Intended Purpose	The disposable vaginal speculum is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures. The vaginal speculum can be used with or without the illuminator.	
Medical Device Conformity Assessment Route Annex	Annex II and Annex III	

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Medical Device Classification	Class I
Medical Device Classification Rule	Rule 13
Standards	Refer to Appendix A

REF #

901071: VAGINAL SPECULUM

59000-LED	59001-LED-B
59001-LED	590XS-LED- B
590XS-LED	59004-LED
59000-LED-B	59004-LED-B

GMDN Code and Term	37468 Vaginal Speculum, single use
UMDNS Code and Term	13666 Specula, Vaginal
Basic UDI-DI	0732094GMN901071F5

Medical Device Classification Rule	Rule 5
Standards	Refer to Appendix A

REF #

901071: VAGINAL SPECULUM

59000	59006
59001	59000- B
59004	59001-B
59005	59004-B
590XS	590XS-B

GMDN Code and Term	37468 Vaginal Speculum, single use
UMDNS Code and Term	13666 Specula, Vaginal
Basic UDI-DI	0732094GMN901071F5

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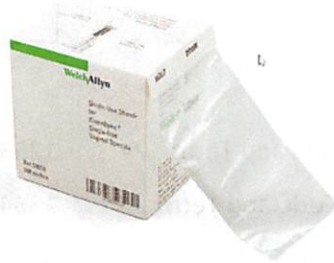
Object of the declaration	Accessories  800 Series KleenSpec® Cordless Illumination System  Disposable Sheaths for KleenSpec Cordless Illumination System
Intended Purpose	When used with the vaginal speculum, the cordless illuminator provides illumination during pelvic examinations and other gynaecological procedures, such as pap smears, dilation and curettage (D&C), biopsy and electro surgery.
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rule 13
Standards	Refer to Appendix A

REF #	901070: VAGINAL SPECULUM LIGHTING SYSTEM 80000, 80010, 80015
GMDN Code and Term	32037 General-purpose light source
UMDNS Code and Term	12340 Light sources
Basic UDI-DI	0732094GMN901070F3

Medical Device Classification	Class I
Medical Device Classification Rule	Rule 5
Standards	Refer to Appendix A

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REF #	901017 ACCESSORY, WOMENS HEALTH 59010 (Illuminator Sheaths)
GMDN Code and Term	12535 Medical Equipment Drape, Single-Use
UMDNS Code and Term	15643 Surgical Drapes, Surgical Instrument
Basic UDI-DI	0732094GMN901017EX

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Approval

Joshua Kim, Sr. Manager, Global Regulatory Affairs	2021. 12. 22	Skaneateles Falls NY
	Date	Place of Issue

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN 60601-1	2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
	EN ISO 10993-1	2010	Biological evaluation of medical devices – Part 1: Evaluation and Testing (ISO 10993-1:2003). NOTE: As applicable, the following standards, as invoked by biological evaluation per EN ISO 10993-1: EN ISO 10993-5:2009, Biological evaluation of medical devices — Part 5: Tests for in-vitro cytotoxicity (ISO 10993-5:2009). EN ISO 10993-10: 2010, Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2010)
	EN 60601-1-2	2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests [IEC 60601-1-2:2014 (4th Edition)]
	EN 60601-1-6	2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability (IEC 60601-1-6:2010+A1:2013)
	EN 62366-1	2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices (IEC 62366:2007+A1:2014)
	EN ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements (ISO 15223-1:2016).

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Directive 2011/65/EU + (EU) 2015/863	EN IEC 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances