

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

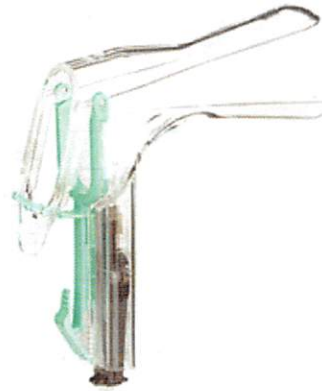
ISO 13485 #314505 MP2016 Expiry Date: 2022-12-08

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



DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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Medical Device Classification	Class I																								
Medical Device Classification Rule	Rule 13																								
Standards	Refer to Appendix A																								
<table border="1"> <tr> <td>REF</td> <td>#</td> <td colspan="2" style="text-align: center;">901071: VAGINAL SPECULUM</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">59000-LED</td> <td style="text-align: center;">59001-LED-B</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">59001-LED</td> <td style="text-align: center;">590XS-LED- B</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">590XS-LED</td> <td style="text-align: center;">59004-LED</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">59000-LED-B</td> <td style="text-align: center;">59004-LED-B</td> </tr> </table>	REF	#	901071: VAGINAL SPECULUM				59000-LED	59001-LED-B			59001-LED	590XS-LED- B			590XS-LED	59004-LED			59000-LED-B	59004-LED-B					
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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																								
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Basic UDI-DI	0732094GMN901071F5																								

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Accessories

Object of the declaration



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	#
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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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DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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901017 ACCESSORY, WOMENS HEALTH

REF

#

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

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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
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