EU Declaration of Conformity (DoC)

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EU DoC ID	**80016468 Rev. Y**

Manufacturer Name and Address:

Welch Allyn, Inc.
4341 State Street Road

Skaneateles Falls, NY 13153 USA

Manufacturer Single Registration Number (SRN): US-MF-000013394

Authorised Representative Name and Address:

Welch Allyn Limited

Navan Business Park, Dublin Road

Navan, County Meath, C15 AW22, Ireland

Authorised Representative Single Registration Number (SRN): IE-AR-000000768

+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++

Other relevant Directives, Regulations and Union Legislations that the device is in conformity with:

- Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.
- 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 (CCV).
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to making available on the market of radio equipment, 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).

Common Specifications Applied:

Article 3.1(a)	EN/IEC 60601-1 Medical electrical equipment, Part 1: General requirements for basic safety	2005 +A2:2020
	EN 62311 Assessment of Electronic and Electrical Equipment related to Human Exposure Restrictions for Electromagnetic Fields (0Hz-300GHz)	2008
Article 3.1(b)	EN 301 489-1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and	V2.2.3

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	services — Part 1: Common technical requirements. Harmonised standard covering the essential requirements of Article 3.1(b) of Directive 2014/53/EU and essential requirements of Article 6 of Directive 2014/30/EU.	
	EN 301 489-3 Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services - Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9kHz and 246 GHz; Harmonised Standard covering the essential requirements of Article 3.1 (b) of Directive 2014/53/EU	V2.3.2
Article 3.2	EN 303 417 Wireless power transmission systems, using technologies other than radio frequency beam in the 19 - 21 kHz, 59 - 61 kHz, 79 - 90 kHz, 100 - 300 kHz, 6 765 - 6 795 kHz ranges; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	V1.1.1

Product/Trade Name and Product Code or REF. number:

Device: Single-Use LED Vaginal Specula

REF	#	Description
590XS-LED	901071	KleenSpec 590 Premium LED Vaginal Speculum XS Case
590XS-LED-B	901071	KleenSpec 590 Premium LED Vaginal Speculum XS Box
59000-LED	901071	KleenSpec 590 Premium LED Vaginal Speculum Small Case
59000-LED-B	901071	KleenSpec 590 Premium LED Vaginal Speculum Small Box
59001-LED	901071	KleenSpec 590 Premium LED Vaginal Speculum Medium Case
59001-LED-B	901071	KleenSpec 590 Premium LED Vaginal Speculum Medium Box
59004-LED	901071	KleenSpec 590 Premium LED Vaginal Speculum Large Case
59004-LED-B	901071	KleenSpec 590 Premium LED Vaginal Speculum Large Box

Intended Purpose/Use: 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 intended users of the device are clinicians who are qualified to perform a pelvic exam. The intended environment is any location where a pelvic exam is conducted (hospital, clinic, office, long term care facility, etc.). The intended patients are all female patients who are eligible for a pelvic exam and who the clinician determines will fit with the size specula that are available (extra-small, small, medium, large).

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Device Risk Class: Class 1, Rule 13

Product Basic UDI-DI Number: 0732094GMN901071F5

Product/Trade Name and Product Code or REF. number:

Device: Disposable Vaginal Specula

REF	#	Description
590XS	901071	KleenSpec 590 Premium Vaginal Speculum XS Case
590XS- B	901071	KleenSpec 590 Premium Vaginal Speculum XS Box
59000	901071	KleenSpec 590 Premium Vaginal Speculum Small Case
59000-B	901071	KleenSpec 590 Premium Vaginal Speculum Small Box
59001	901071	KleenSpec 590 Premium Vaginal Speculum Medium Case
59001-B	901071	KleenSpec 590 Premium Vaginal Speculum Medium Box
59004	901071	KleenSpec 590 Premium Vaginal Speculum Large Case
59004-B	901071	KleenSpec 590 Premium Vaginal Speculum Large Box
59005	901071	KleenSpec 590 Smoke Tube Vaginal Speculum Small Case
59006	901071	KleenSpec 590 Smoke Tube Vaginal Speculum Medium Case

Intended Purpose/Use: 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.

The intended users of the device are clinicians who are qualified to perform a pelvic exam. The intended environment is any location where a pelvic exam is conducted (hospital, clinic, office, long term care facility, etc.). The intended patients are all female patients who are eligible for a pelvic exam and who the clinician determines will fit with the size specula that are available (extra-small, small, medium, large).

Device Risk Class: Class 1, Rule 5

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Product Basic UDI-DI Number: 0732094GMN901071F5

Product/Trade Name and Product Code or REF. number:

Accessories: Vaginal Speculum Lighting Systems

REF	#	Description
80000	901070	KleenSpec Vaginal Speculum Cordless Illuminator
80010	901070	Cordless Illuminator with Charge Station Domestic
80015	901070	Cordless Illuminator with Charge Station International
74010	901070	Charging Station Cordless Illuminator Domestic
74015	901070	Charging Stattion Cordless Illuminator International
74011	901070	Charging Station for Cordless Illuminator

Intended Purpose/Use: When used with the KleenSpec Disposable Vaginal Speculum (vaginal speculum), Welch Allyn

KleenSpec 800 Series Cordless Illumination System (the illuminator) provides illumination during Pelvic examinations and other gynecological procedures, such as pap smears, dilation and curettage (D&C) biopsy, and electrosurgery.

The intended users of the device are clinicians who are qualified to perform a pelvic examination.

The intended environment is any location where a pelvic examination is conducted (hospital, clinic, office, long term care facility, etc.). The intended patients are all female patients who are eligible for a pelvic examination and who the clinician determines will fit with the size specula that are available (extra small, small, medium, large).

Device Risk Class: Class 1 Rule 13

Product Basic UDI-DI Number: 0732094GMN901070F3

Product/Trade Name and Product Code or REF. number:

Accessories: Vaginal Speculum Single-Use Sheaths

REF	#	Description
59010	901017	Cordless Illuminator Single-Use Sheath

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Intended Purpose/Use: The Vaginal Speculum Single-Use sheaths help reduce the risk of cross contamination that covers the illumination cord.
Device Risk Class: Class 1 Rule 5
Product Basic UDI-DI Number: 0732094GMN901017EX
MDR EU Certificate(s) No.: N/A Class 1 Device
Conformity Assessment Description/Annexes: Annex II + Annex III
Notified Body Name and Address: N/A, It's a Class 1 device Notified Body Identification Number: N/A
+++ This Declaration is made on the following basis: • For devices with a MDR EU Certificate issued by a Notified Body: o The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate. o The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate. • For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature. • Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR). • Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Authorised Signatory:	
Name and Title:	Joseph Olsavsky, Sr. Director Regulatory Affairs
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA.
Date of Issue:	08 April 2025

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Signature:	JOSEPH OLSAVSKY *Electronically signed by: JOSEPH OLSAVSKY* *Reason: I approve this document* *Date: Apr 9, 2025 11:15 EDT*

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Version	Description	Author	Date
A	Initial Release – converted from DOC-MDD-121 Rev. 3	C. Picard	2010-10-19
B	Converted to format MPD FCD-0011 Rev. 5. Updated as part of effort to move all DoCs into SAP and to update all DQS certificate numbers that have changed.	S. Schmidt	2011-09-14
C	Add 580 specs: 58008, 78600-B Update format to rev 7	Mark S. Alsberge	2012-01-12
D	Added Extra-Small, Remove 580 Specs (See DIR 80017151)	Mark S. Alsberge	2012-04-30
E	Revised to include all current CE marked KleenSpec vaginal specula model types/configurations. Removed illumination systems (now within DoC 80017151). Corrected Safety report designations to IEC. Corrected GMDN & UMDNS codes	Jamie Strong	2013-11-18
F	Added Annex listing to the DoC Updated to new template	Mark Alsberge	2014-04-08
G	Updated to new format, added RoHS	Scott Hulik	2014-07-08
H	Deleted 58601 Transferred to new DoC Template	M. McGovern	2018-12-06
J	Updated for EUMDR	C. Lefancheck	2020-04-20
K	Rev'd for EUMDR	C. Lefancheck	2021-06-15
L	Updated for RoHS3	K Ockenfels	2021-07-21
M	Updated for RoHS#, Added SRN and Rev Table history	K. Ockenfels	2021-08-17
N	Correction and deleted EN1041	J. Kim	2021-08-23
O	Not used	K. Love/S. Co	2021-11-05
P	Transfer to new format. Add Intended Purpose statement.	K Ockenfels	2021-11-08

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Q	Not used	D. Sharma	2022-12-07
R	Update DoC expiration date to align with EN ISO 13485 certificate.	D. Sharma	2022-12-07
S	Transfer to new template. Added product names adjacent to product codes.	E. Jones	2024-03-15
T	Minor formatting changes/ errors and correcting date code format to YYYY-MM-DD for certificate expiry date.	E. Jones	2024-04-03
U	Added Charging station PNs 74010 and 74015 since it is classified under EUMDR class 1(PCF DIR 60138576) and transferred to new Baxter template	Farees Sultana	02 October 2024
W	Addition of RED directive and RoHS3 and common specifications related to the illumination system.	E. Jones	19 Feb 2025
Y	Added PN 74011.	Farees Sultana	08 April 2025