

**MANUFACTURER'S DECLARATION OF CONFORMITY****AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002****DECLARATION OF CONFORMITY PROCEDURES**

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

**Manufacturer's name:** Welch Allyn, Inc.  
**Business address:** 4341 State Street Road  
 Skaneateles Falls, NY 13153-0220  
 U.S.A.  
**Medical device(s):** KleenSpec® Single Use LED Vaginal Speculum

**#** 901071 Vaginal Speculum

See Appendix 1 for a list

**Classification:** Class I

**GMDN code and term:** 37468 Vaginal Speculum, single use

**Scope of application:** All

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

**Full quality assurance**

**procedures certificate:** 314505 MP2016


**Standards applied:**

| Standard         | Version       | Title  |
|------------------|---------------|--|
| EN ISO 14971     | 2019          | Medical Devices- Application of Risk Management to Medical Devices   |
| EN 63000         | 2018          | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances   |
| EN ISO/ISO 13485 | 2016          | MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS FOR REGULATORY PURPOSES  |
| EN/IEC 60601-1   | 2005          | MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE   |
| EN/IEC 60601-1-2 | 2014          | MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS |
| EN/IEC 60601-1-6 | 2010/3ED 2010 | MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY   |

|                |                     |  |
|----------------|---------------------|--|
|                |                     | AND ESSENTIAL PERFORMANCE - COLLATERAL<br>STANDARD: USABILITY  |
| EN/IEC 60086-4 | 2007                | Primary Batteries. Safety of lithium batteries.  |
| EN/IEC 62281   | 2013/2ED<br>2012    | SAFETY OF PRIMARY AND SECONDARY<br>LITHIUM CELLS AND BATTERIES DURING<br>TRANSPORT                               |
| EN/IEC 62321-1 | 2013/2013           | Determination of certain substances in<br>electrotechnical products – Part 1: Introduction<br>and overview       |
| EN/IEC 62471   | 2008/1 ED<br>2006   | PHOTOBIOLOGICAL SAFETY OF LAMPS AND<br>LAMP SYSTEMS  |
| EN ISO 10993-1 | 2009 + Corr<br>2010 | Biological evaluation of medical devices - Part<br>1: Evaluation and testing within a risk<br>management process |

Authorised signatory:

  
Joshua Kim  
Senior Manager, Regulatory Affairs

  
Date



Appendix 1 –Products

| Part Number | Description                              | GMDN Code                          |
|-------------|--|------------------------------------|
| 58000S-B    | SUCTION TUBE - 40 CM                     | 37468 Vaginal Speculum, single use |
| 58001S-B    | 580 V-SPEC,MED SH, SINGLE BOX            | 37468 Vaginal Speculum, single use |
| 58004S-BAU  | 586 V-SPEC,SM,SINGLE BOX                 | 37468 Vaginal Speculum, single use |
| 58600-B     | KLEENSPEC 590 PREMIUM VAG SPEC SM CASE   | 37468 Vaginal Speculum, single use |
| 59000       | KLEENSPEC 590 PREMIUM VAG SPEC SM BOX    | 37468 Vaginal Speculum, single use |
| 59000-B     | KLEENSPEC 590 PREMIUM VAG SPEC SM BOX    | 37468 Vaginal Speculum, single use |
| 59000-LED   | KLEENSPEC 590 PREMIUM LED VAG SPEC SM CS | 37468 Vaginal Speculum, single use |
| 59000-LED-B | KLEENSPEC 590 PREMIUM LED VAG SPEC SM BX | 37468 Vaginal Speculum, single use |
| 59001       | KLEENSPEC 590 PREMIUM VAG SPEC MD CASE   | 37468 Vaginal Speculum, single use |
| 59001-B     | KLEENSPEC 590 PREMIUM VAG SPEC MD BOX    | 37468 Vaginal Speculum, single use |
| 59001-LED   | KLEENSPEC 590 PREMIUM LED VAG SPEC MD CS | 37468 Vaginal Speculum, single use |
| 59001-LED-B | KLEENSPEC 590 PREMIUM LED VAG SPEC MD BX | 37468 Vaginal Speculum, single use |
| 59004       | KLEENSPEC 590 PREMIUM VAG SPEC LG CASE   | 37468 Vaginal Speculum, single use |
| 59004-B     | KLEENSPEC 590 PREMIUM VAG SPEC LG BOX    | 37468 Vaginal Speculum, single use |
| 59004-LED   | KLEENSPEC 590 PREMIUM LED VAG SPEC LG CS | 37468 Vaginal Speculum, single use |
| 59004-LED-B | KLEENSPEC 590 PREMIUM LED VAG SPEC LG BX | 37468 Vaginal Speculum, single use |
| 59005       | KLEENSPEC 590 SMKE TUBE VAG SPEC SM CASE | 37468 Vaginal Speculum, single use |
| 59005-BAU   | KLEENSPEC 590 SMKE TUBE VAG SPEC SM BOX  | 37468 Vaginal Speculum, single use |
| 59006       | KLEENSPEC 590 SMKE TUBE VAG SPEC MD CASE | 37468 Vaginal Speculum, single use |
| 59006-BAU   | KLEENSPEC 590 SMKE TUBE VAG SPEC MD BOX  | 37468 Vaginal Speculum, single use |
| 590XS       | KLEENSPEC 590 PREMIUM VAG SPEC XS CASE   | 37468 Vaginal Speculum, single use |
| 590XS-B     | KLEENSPEC 590 PREMIUM VAG SPEC XS BOX    | 37468 Vaginal Speculum, single use |
| 590XS-LED   | KLEENSPEC 590 PREMIUM LED VAG SPEC XS CS | 37468 Vaginal Speculum, single use |
| 590XS-LED-B | KLEENSPEC 590 PREMIUM LED VAG SPEC XS BX | 37468 Vaginal Speculum, single use |