Welch Allyn Australia (Pty) Ltd.
Unit 5, 38 – 46 South Street
Rydalmere NSW 2116

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.: 80020831 Version: B

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.
Product name:	Illuminator
REF	901025 ILLUMINATOR, HAND HELD 901000 ACCESSORY/COMPONENT
#	23557, 26030, 26035, 26038, 26530, 26535, 27000, 27050.
Classification:	1
GMDN code and term:	32037 – Light source, general-purpose
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.

Standards applied:

ISO 14971	2009	Medical Devices- Application of Risk Assessment to medical devices
ISO 13485	2003	Medical devices - Quality management systems - Requirements for regulatory purposes
IEC 60601-1 (incl. Amendments)	1990	Medical Electrical Equipment- part 1: General requirements for basic safety and essential requirements
IEC 60601-1-1	2000	Medical Electrical Equipment- part 1-1-General requirements for safety- Collateral Standard: Safety requirements for Medical Electrical Equipment
IEC 60601-1-2	2004	Medical Electrical Equipment- part 1-2- General requirements for safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Test
IEC 60601-1-6	2004	Medical Electrical Equipment- part 1-6- General requirements for safety- Collateral Standard: Usability
EN 62366	2008	Medical devices- Application of usability engineering to medical devices

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Standards applied:

ISO 10993-1	2003	Biological evaluation of medical devices- Part 1: Evaluation and testing
EN 980	2008	Symbols for use in the labelling of medical devices
EN 1041	2008	Information supplied by the manufacturer of medical devices

Authorised Signatory:

Joshua Kim Sr. Manager, Regulatory Affairs

2016-08-10
Date

Skaneateles Falls, NY USA
Place of Issue

This authorisation is given in the signatory's capacity as representative of the "Manufacturer" (as recorded on page 1 of this declaration)