

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 USA 13153-0220
Medical device(s): Illuminator
 REF: 901025 ILLUMINATOR, HAND HELD
 See Appendix 1 for a list
Classification: Class I
GMDN code and term: 36761 Skin Transilluminator
 12276 Light Examination
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/ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO/ISO 14971	2012/2ED 2007	Medical Devices - Application of Risk Management to Medical Devices
EN/IEC 60601-1	2006/ 2005+A1	Medical Electrical Equipment - Part 1: General Requirements for Safety
EN/IEC 60601-1-2	4ED 2014- 02-25	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
EN/IEC 60601-1-6	2010/3ED 2010	Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability
IEC 60601-1-6	2004	Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability
EN/IEC 62366	2008	Medical Devices – Application of Usability Engineering to Medical Devices

Standards applied:

Standard	Version	Title
EN ISO 10993-1	2009 + Corr 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process



Joshua Kim
Senior Manager, Regulatory Affairs

2021.09.22

Date

Appendix 1 –Products

Part Number	Description	GMDN Code	Used in Sets
22009	POLY SPECULUM 9MM	12267 Light Illumination	NA
23557	ILLUMIN SECTION ONLY	12267 Light Illumination	NA
23857	BBO THROAT ILLUMINATOR FINISHED SET	12267 Light Illumination	NA
26330	MAGNIFYING LENS F/26035	12267 Light Illumination	NA
26530	3.5V HALOGEN NASAL ILLUMINATOR	12267 Light Illumination	NA
26531	NASAL ILLULM. ASSEMBLY	12267 Light Illumination	NA
26535	NASAL ILLUM SECT ONLY	12267 Light Illumination	NA
26538	FBR OPTIC NASAL ILLUMINATOR MACROVIEW	12267 Light Illumination	NA
26550	NASAL ILLUMINATOR SECTION ONLY	12267 Light Illumination	NA
41100	3.5V FO FINNOFF TRANSILLUM	36761 Skin Transilluminator	18335-SSP5
41101	3.5V FINNOFF TRANSILL W/FILTER	36761 Skin Transilluminator	NA
41102	COBALT BLUE FILTER	36761 Skin Transilluminator	NA
43300	3.5V CURVED TRANSILLUMINAT	36761 Skin Transilluminator	NA
28100	3.5V HAL TONGUE BLADE HOLDER	12267 Light Illumination	NA