

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Welch Allyn, Inc.

4341 State Street Road
Business address: Skaneateles Falls, NY 13153-0220
U.S.A.

Medical device(s): Welch Allyn Wall and Mobile Aneroid Sphygmomanometer
901040 GAUGE, MOUNTED

Classification: I(m)

GMDN code and term: 16156 - Sphygmomanometer, Aneroid

Scope of application: All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate: 314505 MR2

Design examination certificate (if applicable): Not Applicable

| Standards applied: | Standard | Version | Title |
|--------------------|----------------|--------------|---|
| | EN ISO 13485 | 2012 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| | EN ISO 14971 | 2012 | Medical devices - Application of risk management to medical devices |
| | EN/ISO 81060-1 | 2012 | Non-invasive sphygmomanometers- Part 1: Requirements and test methods for non-automated measurement type. |
| | ISO 15223-1 | 2012 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2012) |
| | EN 1041 | 2008 + A2013 | Information supplied by the manufacturer with medical devices |

Authorised signatory:



Joshua Kim
Senior Manager, Regulatory Affairs

2018.09.05
Date