

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.
Business address: 4341 State Street Road
Skaneateles Falls, NY USA 13153-0220
Medical device(s): Welch Allyn Wall and Mobile Aneroid Sphygmomanometer
901040 GAUGE, MOUNTED
901091 MOUNTED GAUGE AND CUFF(S)
See Appendix 1 for a list
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 MP2016
EC Certificate: 314505 MR2
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Standards applied:	Standard	Version	Title
	EN ISO 13485	2016	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)

Standards applied:	Standard	Version	Title
	EN 1041	2008 + A2013	Information supplied by the manufacturer with medical devices

Authorised signatory:



2021-06-10

Joshua Kim
Senior Manager, Global Regulatory Affairs

Date

Appendix 1 - List

Part Number	Description	GMDN Code
7670-01	767 WALL GAGE,ADULT CUFF	16156 - Sphygmomanometer, aneroid
7670-01CB	767 WALL GAGE,ADULT 2-PC CUFF	16156 - Sphygmomanometer, aneroid
7670-01S	767 WALL GAUGE ONLY PLATFORM COLORS	16156 - Sphygmomanometer, aneroid
7670-02	767 WALL GAGE,WITH 8' TUBING	16156 - Sphygmomanometer, aneroid
7670-10	767 MOBILE GAGE,ADULT,5 LEG BASE	16156 - Sphygmomanometer, aneroid
7670-10CB	767 MOBILE GAGE,ADULT,2-PC,5 LEG BASE	16156 - Sphygmomanometer, aneroid
7670-16	767 DESK GAGE, ADULT CUFF	16156 - Sphygmomanometer, aneroid