

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Manufacturer's Name and Business Address: Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153 USA

EC REP Regulatory Affairs Representative
Welch Allyn Limited
Navan Business Park
Dublin Road
Navan, County Meath
Republic of Ireland

Product Name^{1,3}: Welch Allyn Aneroid Sphygmomanometers

REF^{1,3} 901041, GAUGE, HAND HELD

#^{1,3} DS44, DS44A
DS45, DS45A, DS45T
DS48, DS48A
DS58
DS-6501-300
DS-6601-300
DS-5401-300, DS-5402-300, DS-54L1-300, DS-54L2-300
DS-5501-300, DS-5502-300, DS-5511-300RMC, DS-5512-300RMC, DS-5521-300, DS-5541-300, DS-5561-300
DS-5601-300, DS-5602-300

Radio equipment²: Not applicable, no radio

Object of the declaration²: Not applicable, no radio

Accessories and components²: Not applicable, no radio

Medical Device Conformity Assessment Route Annex¹: II

Medical Device Classification¹: I(m)

¹ applicable to the medical devices directive, 93/42/EEC

² applicable to the radio equipment directive, 2014/53/EU

³ applicable to the RoHS directive, 2011/65/EU

Medical Device Classification Rules ¹ :	I		
GMDN Code and Term ¹ :	16156, Sphygmomanometer, aneroid		
UMDNS Code and Term ¹ :	13102, Pressure Measuring Units		
Notified Body ¹ : (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2		
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title	
	EN/ISO 81060-1	Non-invasive sphygmomanometers- Part 1: Requirements and test methods for non-automated measurement type.	

Authorised Signatory:



Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2019-03-21

Date

Navan

Place of Issue

¹ applicable to the medical devices directive, 93/42/EEC

² applicable to the radio equipment directive, 2014/53/EU

³ applicable to the RoHS directive, 2011/65/EU