DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016902 Version: G

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:	Welch Allyn Aneroid Sphygmomanometers
REF	901041, GAUGE, HAND HELD
#	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
Medical Device Conformity Assessment Route Annex:	II
Medical Device Classification:	I(m)
Medical Device Classification Rules:	1
GMDN Code and Term:	16156, Sphygmomanometer, aneroid
UMDNS Code and Term	13102, Pressure Measuring Units
Notified Body:	DQS Medizinprodukte GmbH,

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(CE 0297)	August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2	
Standards Applied:	EN/ISO 81060-1	Non-invasive sphygmomanometers- Part 1: Requirements and test methods for non-automated measurement type.

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2016-05-30
Date

Navan
Place of Issue