

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



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

Product Name: Welch Allyn Aneroid Sphygmomanometers



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,



DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016902

Version: G

(CE 0297)

August-Schanz-Str.21, 60433 Frankfurt am Main

EC-certificate No. 314505 MR2

Standards

EN/ISO 81060-1

Non-invasive sphygmomanometers- Part 1:

Applied:

Requirements and test methods for non-automated measurement type.

Authorised Signatory:

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2016-05-30

Date

Navan

Place of Issue