

Welch Allyn DECLARATION OF CONFORMITY

SAP DIR No.: 80017189

Version: C

We declare, under our sole responsibility, that the product listed below conforms to the provisions of 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 |
| EC REP | Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland |
| Product Name: | Wall and Mobile Sphygmomanometers |
| REF | Mechanical Sphygmomanometer. 7670-X, where X corresponds to the following extensions: 01, 01C, 01CB, 01CCB, 01KPA, 01LFM, 01M, 01R, 01S, 01W, 01WS, 02, 03, 03CB, 03K, 04, 04CB, 10, 10CB, 10KPA, 11, 11CB, 16, 70, 70KPA 77435-2X |
| Annex: | V |
| Classification: | I measuring |
| Classification Rules: | 1 |
| GMDN Code and Term: | 16156 Sphygmomanometer, aneroid |
| UMDNS Code and Term | 13102 Instruments designed to measure the pressure of liquids, gases, and/or vapors. |
| Notified Body: (CE 0297) | DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main certificate 314505 MR5m |

Welch Allyn® DECLARATION OF CONFORMITY

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|--------------------|-----------|--|
| Standards Applied: | EN 1060-1 | Non-invasive sphygmomanometers – Part 1 General requirements |
| | EN 1060-2 | Non-invasive sphygmomanometers – Part 2: Supplementary requirements for mechanical sphygmomanometers |

Authorised Signatory:



Kevin Crossen, Regulatory Affairs Representative

2011-10-21
Date

WelchAllyn® DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80017189

Version: G

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

EC REP

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

Product Name: Welch Allyn Wall and Mobile Aneroid Sphygmomanometer

REF

901040 GAUGE, MOUNTED

#

7670-01S, 7670-02, 7670-03K

Annex: II

Classification: I measuring

Classification Rules: 1

GMDN Code and Term: 16156 Sphygmomanometer, aneroid

UMDNS Code and Term: 13102
Pressure Measuring Units

Notified Body: (CE 0297) DQS Medizinprodukte GmbH,
August-Schanz-Str.21, 60433 Frankfurt am Main
EC-certificate No. 314505 MR2

WelchAllyn® **DECLARATION OF CONFORMITY**
(in accordance with ISO/IEC 17050-1)


SAP DIR No.: 80017189

Version: G

Standards Applied: 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}

2015-06-22
Date

Navan
Place of Issue