



DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80017189

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



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



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



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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}

Date

Place of Issue