

Welch Allyn[®] MANUFACTURER'S DECLARATION OF CONFORMITY

Made in accordance with Council Directive 93/42/EEC

<i>Reference:</i>	DOC-MDD-137, Revision 2	DIR No.: Not Applicable
<i>Manufacturer's Name:</i>	Welch Allyn, Inc.	
<i>Business Address:</i>	4341 State Street Road Skaneateles Falls, NY 13153-0220	
EC REP	Regulatory Affairs Manager – EMEA Welch Allyn, Ltd. Navan Business Park Dublin Road Navan, County Meath Republic of Ireland	
<i>Annex:</i>	V	
<i>Medical Device(s):</i>	Mechanical Sphygmomanometer. DS44-X, where X corresponds to the following extensions: 09, 09C, 09CB, 09CV, 09CVW, 09CW, 09P, 09PC, 09PCB, 09CBW, 09PCBW, 09PCV, 09PCVW, 09PCW, 09PV, 09PVW, 09V, 09VW, 09W, 09PW, 10, 10C, 10CV, 10CVW, 10CW, 10V, 10VW, 10W, 11, 11C, 11CB, 11CBW, 11CN, 11CV, 11CVW, 11CW, 11V, 11VW, 11W, 12, 12C, 12CB, 12CBW, 12CV, 12CVW; 12CW, 12V, 12VW, 12W, 13CB, 13CBW, MC. DS45-X, where X corresponds to the following extensions: 09, 09C, 09CB, 09CE, 09CW, 09CWE, 09E, 09P, 09PC, 09CB, 09CBW, 09PCB, 09PCBW, 09PCB, 09PCE, 09PCW, 09PCWE, 09PE, 09PW, 09PWE, 09W, 09WE, 10, 10C, 10CE, 10CW, 10CWE, 10E, 10W, 10WE, 11, 11C, 11CB, 11CBW, 11CE, 11CW, 11CWE, 11E, 11W, 11WE, 12, 12C, 12CB, 12CBW, 12CE, 12CW, 12CWE, 12E, 12W, 12WE, 13CB, 13CBW, MC.	
<i>Classification:</i>	I (measuring)	
<i>Classification Rules:</i>	1	
<i>GMDN Code and Term:</i>	16156 – Sphygmomanometer, aneroid	
<i>Scope of Application:</i>	All	
<i>Quality Sys. Certificate:</i>	DQS GmbH certificate 314505 MP23 indicating conformance to DIN EN ISO 13485:2003.	

Reference:

DOC-MDD-137, Revision 2

DIR No.: Not applicable.

Standards Applied:

EN 1060-1 EN 1060-2 EN 980 EN 1041

Authorised Signatory:



Huy Doan, Director of Corporate Regulatory Affairs

2010-03-31
Date