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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, 2253 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-5511-189MH, DS-5512-189MH 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

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

Authorised Signatory:

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Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative}	Date	Navan Place of Issue

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Document Change History

Version	Description	Author	Date
A	Initial Release, copied from DOC-MDD-137 Rev. 2	S. Schmidt	2010-03-30
B	<p>Updated to match STED 60039048, which is being reviewed and loaded into SAP.</p> <p>Updated to latest format, MPD FCD-0011 ver. 7.</p> <p>Added: DS44, DS44A, DS44A-001, DS44-X, where X corresponds to the following extensions: 09PW.</p> <p>Added: DS45, DS45A, DS45T, DS45-X, where X corresponds to the following extensions: 11CBT, -11L-001.</p> <p>Deleted: DS44-X, where X corresponds to the following extensions: 09CBW, 09PCBW, 11CBW, 12CBW, 13CBW.</p> <p>Deleted: DS45-X, where X corresponds to the following extensions: 09CE, 09CWE, 09E, 09CBW, 09PCBW, 09PCE, 09PCWE, 09PE, 09PWE, 09WE, 10CE, 10CWE, 10E, 10WE, 11CBW, 11CE, 11CWE, 11E, 11WE, 12CBW, 12CE, 12CWE, 12E, 12WE, 13CBW.</p> <p>All of the materials being deleted were never loaded into SAP.</p>	S. Schmidt	2012-10-19
C	<p>Old EC Cert number was referenced, changed to 314505 MR2</p> <p>Changed the Annex to II</p>	F. Butler	2014-03-05

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D	<p>Merged all handheld Durashock gauges onto one DoC. The following DoCs are being replaced by this DoC: 80016414 and 80016585.</p> <p>Updated DoC to only include those part numbers that are CE marked. Some kits contain cuffs and gauges so, according to an internal rule to not CE mark kits that contain multiple medical devices, these material numbers are no longer CE marked and are removed from the DoC.</p>	S. Schmidt	2014-10-08
E	<ol style="list-style-type: none"> 1) Updated “product name” to <i>Welch Allyn Aneroid Sphygmomanometers</i> after agreement with Fiona, Gary and Susan since multiple catalogue names may cause confusion 2) Added Welch Allyn unique “REF” description 3) Added Welch Allyn unique “#” re-order symbol numbers 4) Operations confirmed that listed “#” numbers correlate to device numbers listed within test report 60066584. 5) Corrected UMDNS code term 6) Abandoned 80016414 & 80016585 with READ ME pointer to this DoC. 7) Updated standards list from EN 1060-1 & EN 1060-2 to EN/ISO 81060-1 	Jamie Strong	2015-05-22
F	Updated due to admin error with it being released in SAP without signature	M.McGovern	2015-08-13

#	Description
DS44	DURASHOCK, GAGE ONLY
DS45	DURASHOCK, GAGE ONLY
DS45T	DURASHOCK, GAGE ONLY, TYCOS BUMPER
2253	PSS-45CB GAUGE W/ADAPTER
DS48	DS48 GAUGE ONLY
DS48A	DS48A GAUGE ONLY
DS58	DS58 GAUGE ONLY
DS-5401-300	DS-54 MANOMETER ONLY WITH
DS-5402-300	DS-54 MANOMETER ONLY WITH
DS-54L1-300	DS54 MANOMETER WITH SPOON W/O CUFF
DS-54L2-300	DS-54 MANOMETER ONLY WITH SPOON
DS-5501-300	DS-55 MANOMETER CHROME HLIGHTS
DS-5502-300	DS-55 MANOMETER ONLY CHROME
DS-5511-300RMC	DS55, 1-TUBE, W/O CUFF, ROSER
DS-5512-300RMC	DS55, 2-TUBE, W/O CUFF, ROSER
DS-5521-300	DS-55 MANOMETER BLUE HLIGHTS
DS-5541-300	DS-55 MANOMETER RED HLIGHTS
DS-5561-300	DS-55 MANOMETER YELLOW HLIGHTS
DS-5511-189MH	DS55 SILVER LINE 1 TUBE MEDIKA HOF LOGO
DS-5512-189MH	DS55 SILVER LINE 2 TUBE MEDIKA HOF LOGO
DS-5601-300	DS-56 MANOMETER ONLY SINGLE
DS-5602-300	DS-56 MANOMETER ONLY WITH DBL
DS-6501-300	DS-65 TRIGGER MODEL SILVER-MAN
DS-6601-300	DS-66 TRIGGER MODEL PREMIUM

This Annex is only valid in connection with the above mentioned Declaration of Conformity.