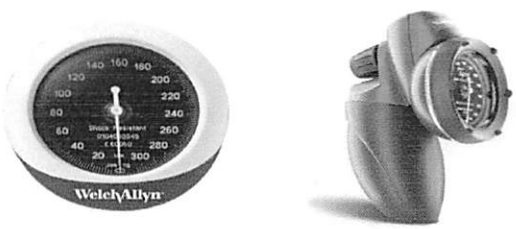
DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

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.

Document Number 80016902	Version K	
Product Name	Welch Allyn Aneroid Sphygmomanometers	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
EC Certificates Declaration of Conformity Validity	EC Certificate 314505 MR2 Expiry Date: 2024-05-26	
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road Navan, Co. Meath C15 AW22, Ireland	SRN: IE-AR-000000768
REF #	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 901040 GAUGE, MOUNTED	
Radio equipment	N/A	
Object of the declaration	 Aneroid Sphygmomanometers	
Intended Purpose	N/A	

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Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	I(m)
Medical Device Classification Rule	1
Standards	See Appendix A
GMDN Code and Term	16156 Aneroid manual sphygmomanometer
UMDNS Code and Term	13102 Manometers
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

Authorised Signatory

Joshua Kim
Senior Manager
Global Regulatory Affairs

2021-10-13
Date

Skaneateles Falls NY, USA
Place of Issue

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Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN ISO 81060-1	2012	Non-invasive sphygmomanometers_- Part_1: Requirements and test methods for non-automated measurement type
	EN 62366-1	2015	Medical devices_- Application of usability engineering to medical devices
	EN ISO 10993-1	2009	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects_- Good clinical practice
	EN ISO 15223-1	2016	Medical devices_- Symbols to be used with medical device labels, labelling and information to be supplied_- Part_1: General requirements
	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes

Document Change History

Version	Description	Author	Date
A	Initial Release, copied from DOC-MDD-137 Rev. 2	S. Schmidt	2010-03-30
B	Updated to match STED 60039048, which is being reviewed and loaded into SAP. Updated to latest format, MPD FCD-0011 ver. 7. Added: DS44, DS44A, DS44A-001, DS44-X, where X corresponds to the following extensions: 09PW. Added: DS45, DS45A, DS45T, DS45-X, where X corresponds to the following extensions: 11CBT, -11L-001. Deleted: DS44-X, where X corresponds to the following extensions: 09CBW, 09PCBW, 11CBW, 12CBW, 13CBW. 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. All of the materials being deleted were never loaded into SAP.	S. Schmidt	2012-10-19
C	Old EC Cert number was referenced, changed to 314505 MR2 Changed the Annex to II	F. Butler	2014-03-05
D	Merged all handheld Durashock gauges onto one DoC. The following DoCs are being replaced by this DoC: 80016414 and 80016585. 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.	S. Schmidt	2014-10-08

E	1) Updated "product name" to *Welch Allyn Aneroid Sphygmomanometers* 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
G	Updated due to admin error with it being released in SAP without signature. The following items were deleted from the REF and Annex Sections of the DoC: 2253, DS-5511-189MH, DS-5512-189MH	M. McGovern	2016-05-27
H	Updated to new version of the template	B. Rice	2019-02-26
J	Updated to new Hillrom Template	K.Ockenfels	2021-09-02
K	Updated header, removed accessory section (not needed), added SRN # for Skaneateles.	K. Ockenfels	2021-10-12