DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Document Number 80016679	Version P	
Product Name	Flexiport Cuff (Reuse)	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
Declaration of Conformity Validity	ISO 13485 #314505 MP2016 Expiry Date: 2024-11-07	
EC REP	Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland	SRN: IE-AR-000000768
Object of the declaration	 Flexiport Cuff (Reusable)	
Intended Purpose	Welch Allyn Pediatric through Adult Blood Pressure cuffs are non-invasive blood pressure cuffs intended for use in conjunction with non-automated and automated sphygmomanometers to determine blood pressure in pediatric through adult patients.	
Medical Device Conformity Assessment Route Annex	Annex II and Annex III	
Medical Device Classification	Class I	
Medical Device Classification Rule	Rules 1	
Standards	Refer to Appendix A	

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REF #

901043 BLOOD PRESSURE CUFF, REUSABLE

REUSE-06	CUFF, WA, REUSABLE, SMALL INFANT
REUSE-06-1HP	CUFF, REUS, SM INFANT, 1-TUBE, HP
REUSE-06-1MQ	CUFF, REUS, SM INFANT, 1-TUBE, MQ
REUSE-06-1TP	CUFF, REUS, SM INFANT, 1-TUBE, TP
REUSE-06-1TPE	CUFF, REUS, SM INFANT, 1-TUBE TPE
REUSE-07	CUFF, WA, REUSABLE, INFANT
REUSE-07-1HP	CUFF, REUS, INFANT, 1-TUBE, HP
REUSE-07-1MQ	CUFF, REUS, INFANT, 1-TUBE, MQ
REUSE-07-1TP	CUFF, REUS, INFANT, 1-TUBE, TP
REUSE-07-1TPE	CUFF, REUS, INFANT, 1-TUBE TPE
REUSE-07-2BV	CUFF, REUS, INFANT, 2-TUBE, BV
REUSE-07-2BVC	CUFF, REUS, INFANT, 2-TUBE, BVC
REUSE-07-2MQ	CUFF, REUS, INFANT, 2-TUBE, MQ
REUSE-07-2MF	CUFF, REUS, INFANT, 2-TUBE, MF
REUSE-07-2TP	CUFF, REUS, INFANT, 2-TUBE, TP
REUSE-07-2TPE	CUFF, REUS, INFANT, 2-TB, TPE
REUSE-08	CUFF, WA, REUSABLE, SM CHILD
REUSE-08-1HP	CUFF, REUS SM CHILD 1-TUBE, HP
REUSE-08-1MQ	CUFF, REUS SM CHILD 1-TUBE, MQ
REUSE-08-1SC	CUFF, REUS SM CHILD 1-TUBE, SC
REUSE-08-1TP	CUFF, REUS SM CHILD 1-TUBE, TP
REUSE-08-2BV	CUFF, REUS SM CHILD 2-TUBE, BV
REUSE-08-2BVC	CUFF, REUS SM CHILD 2-TUBE, BVC
REUSE-08-2MF	CUFF, REUS SM CHILD 2-TUBE MF
REUSE-08-2MQ	CUFF, REUS SM CHILD 2-TUBE, MQ
REUSE-08-2TP	CUFF, REUS SM CHILD 2-TUBE, TP
REUSE-08-2TPE	CUFF, REUS SM CHILD 2-TB, TPE
REUSE-09	CUFF, WA, REUSABLE, CHILD
REUSE-09-1HP	CUFF, REUS, CHILD, 1-TUBE, HP
REUSE-09-1MQ	CUFF, REUS, CHILD, 1-TUBE, MQ
REUSE-09-1TP	CUFF, REUS, CHILD, 1-TUBE, TP
REUSE-09-1TPE	CUFF, REUS, CHILD, 1-TUBE, TPE
REUSE-09-2BV	CUFF, REUS, CHILD, 2-TUBE, BV
REUSE-09-2BVC	CUFF, REUS, CHILD, 2-TUBE, BVC
REUSE-09-2MF	CUFF, REUS, CHILD, 2-TUBE MF
REUSE-09-2MQ	CUFF, REUS, CHILD, 2-TUBE, MQ
REUSE-09-2TP	CUFF, REUS, CHILD, 2-TUBE, TP
REUSE-09-2TPE	CUFF, REUS, CHILD, 2-TUBE, TPE
REUSE-10	CUFF, WA, REUSABLE, SM ADULT
REUSE-10-1HP	CUFF, REUS, SM AD, 1-TUBE, HP
REUSE-10-1MQ	CUFF, REUS, SM AD, 1-TUBE, MQ
REUSE-10-1TP	CUFF, REUS, SM AD, 1-TUBE, TP
REUSE-10-1TPE	CUFF, REUS, SM AD, 1-TUBE, TPE
REUSE-10-2BV	CUFF, REUS, SM AD, 2-TUBE, BV
REUSE-10-2BVC	CUFF, REUS, SM AD, 2-TUBE, BVC
REUSE-10-2MF	CUFF, REUS, SM AD, 2-TUBE, MF
REUSE-10-2MQ	CUFF, REUS, SM AD, 2-TUBE, MQ
REUSE-10-2TP	CUFF, REUS, SM AD, 2-TUBE, TP
REUSE-10-2TPE	CUFF, REUS, SM AD, 2-TUBE, TPE
REUSE-11	CUFF, WA, REUSABLE, ADULT

REUSE-11-1HP	CUFF, REUS, ADULT, 1-TUBE, HP
REUSE-11-1MQ	CUFF, REUS, ADULT, 1-TUBE, MQ
REUSE-11-1TP	CUFF, REUS, ADULT, 1-TUBE, TP
REUSE-11-1TPE	CUFF, REUS, ADULT, 1-TUBE, TPE
REUSE-11-2BV	CUFF, REUS, ADULT, 2-TUBE, BV
REUSE-11-2BVC	CUFF, REUS, ADULT, 2-TUBE, BVC
REUSE-11-2MF	CUFF, REUS, ADULT, 2-TUBE, MF
REUSE-11-2MQ	CUFF, REUS, ADULT, 2-TUBE, MQ
REUSE-11-2TP	CUFF, REUS, ADULT, 2-TUBE, TP
REUSE-11-2TPE	CUFF, REUS, ADULT, 2-TUBE, TPE
REUSE-11L	CUFF, WA, REUSABLE ADULT LONG
REUSE-11L-1HP	CUFF, REUS, AD LONG 1-TUBE, HP
REUSE-11L-1MQ	CUFF, REUS, AD LONG 1-TUBE, MQ
REUSE-11L-1TP	CUFF, REUS, AD LONG 1-TUBE, TP
REUSE-11L-1TPE	CUFF, REUS, AD LONG 1-TUBE TPE
REUSE-11L-2BV	CUFF, REUS, AD LONG 2-TUBE, BV
REUSE-11L-2BVC	CUFF, REUS, AD LONG 2-TUBE, BVC
REUSE-11L-2MF	CUFF, REUS, AD LONG 2-TUBE, MF
REUSE-11L-2MQ	CUFF, REUS, AD LONG 2-TUBE, MQ
REUSE-11L-2TP	CUFF, REUS, AD LONG 2-TUBE, TP
REUSE-11L-2TPE	CUFF, REUS, AD LONG 2-TUBE TPE
REUSE-12	CUFF, WA, REUSABLE, LG ADULT
REUSE-12-1HP	CUFF, REUS, LG AD, 1-TUBE, HP
REUSE-12-1MQ	CUFF, REUS, LG AD, 1-TUBE, MQ
REUSE-12-1TP	CUFF, REUS, LG AD, 1-TUBE, TP
REUSE-12-1TPE	CUFF, REUS, LG AD, 1-TUBE, TPE
REUSE-12-2BV	CUFF, REUS, LG AD, 2-TUBE, BV
REUSE-12-2BVC	CUFF, REUS, LG AD, 2-TUBE, BVC
REUSE-12-2MF	CUFF, REUS, LG AD, 2-TUBE, MF
REUSE-12-2MQ	CUFF, REUS, LG AD, 2-TUBE, MQ
REUSE-12-2TP	CUFF, REUS, LG AD, 2-TUBE, TP
REUSE-12-2TPE	CUFF, REUS, LG AD, 2-TUBE, TPE
REUSE-12L	CUFF, WA, REUS, LG ADULT LONG
REUSE-12L-1HP	CUFF REUS LG AD LONG 1-TUBE HP
REUSE-12L-1MQ	CUFF REUS LG AD LONG 1-TUBE MQ
REUSE-12L-1TP	CUFF REUS LG AD LONG 1-TUBE TP
REUSE-12L-1TPE	CUFF REUS LG AD LONG 1-TUBE TPE
REUSE-12L-2BV	CUFF REUS LG AD LONG 2-TUBE BV
REUSE-12L-2BVC	CUFF REUS LG AD LONG 2-TUBE BVC
REUSE-12L-2MF	CUFF REUS LG AD LONG 2-TUBE MF
REUSE-12L-2MQ	CUFF REUS LG AD LONG 2-TUBE MQ
REUSE-12L-2TP	CUFF REUS LG AD LONG 2-TUBE TP
REUSE-12L-2TPE	CUFF REUS LG AD LONG 2-TUBE TPE
REUSE-13	CUFF, WA, REUSABLE, THIGH
REUSE-13-1HP	CUFF, REUS, THIGH, 1-TUBE, HP
REUSE-13-1MQ	CUFF, REUS, THIGH, 1-TUBE, MQ
REUSE-13-1TP	CUFF, REUS, THIGH, 1-TUBE, TP
REUSE-13-1TPE	CUFF, REUS, THIGH, 1-TUBE, TPE
REUSE-13-2BV	CUFF, REUS, THIGH, 2-TUBE, BV
REUSE-13-2BVC	CUFF, REUS, THIGH, 2-TUBE, BVC
REUSE-13-2MF	CUFF, REUS, THIGH, 2-TUBE, MF
REUSE-13-2MQ	CUFF, REUS, THIGH, 2-TUBE, MQ

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	REUSE-13-2TP: CUFF, REUS, THIGH, 2-TUBE, TP REUSE-13-2TPE: CUFF, REUS, THIGH, 2-TUBE, TPE REUSE-ACC-MON: CUFF, REUSE (CHILD, SM ADULT, THIGH) MON PK REUSE-MLT-1: CUFF, REUSE, ADULT MULTIPACK,1-TB REUSE-PED-MON: CUFF, REUSE, PED MONITOR PACK REUSE-FP-BV: CUFF, REUSE, FP WALL PACK REUSE-MLT-2: CUFF, REUSE, ADULT MULTIPACK,2-TB REUSE-FP-MON: CUFF, REUSE, FP MONITOR PACK REUSE-PED-BV: CUFF, REUSE, PED WALL PACK REUSE-MLT: CUFF, REUS, MULTIPACK REUSE-PED-HAND: CUFF, REUSE, PED HAND GAUGE PACK REUSE-FP-HAND: CUFF, REUSE, FP HAND GAUGE PACK
GMDN Code and Term	34978 Blood Pressure Cuff, Reusable
UMDNS Code and Term	11072 Cuffs
Basic UDI-DI	0732094GMN901043EY

Approval

Jeffrey E Thompson
Manager, Global Regulatory Affairs

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
Regulation 2017/745	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 14971	2019	Medical Devices – Application of risk management to medical devices
	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 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing
	EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	EN ISO 20417	2021	Medical Devices – Information to be supplied by the manufacturer
	EN ISO 81060-1	2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non- automated measurement type
	EN ISO 80369-5	2016	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications
	EN 62366-1	2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices

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Document Change History

Version	Description	Author	Date
A	Updated to SAP, Removed the neonate cuffs and FlexiPort Cuffs from DoC. Removed component parts that are not accessories and not supported in the technical file or compliant with MDD labeling.	S. Schmidt	2011-01-07
B	Updated to new format. Updated EU REP address, removed Notified Body since this is a class I product.	S. Schmidt	2011-08-12
C	Added annex for Saudi Arabia submission. Updated to new format. Removed bladders, since these are components and are not CE marked (all 5089-X numbers and 5200-04, 05, 06, and 11, checked pkg labels). Added 4500-01, 4500-200, 5082-21H, 5082-64, 5082-65, 5200-01, 5200-02, 5200-03, 5200-10 (checked all pkg labels include CE mark). Added 2-pc cuffs being transferred from Jungingen to Tijuana.	S. Schmidt	2012-01-10
D	1) Added EN/ISO 81060-1 2) Removed EN 1060-1 and EN 1060-2 since both are formally withdrawn as of May 31, 2015 and all listed cuffs have met EN/ISO 81060-1 (see 60066583) which is in force. 3) Corrected UMDNS code 11072 to identify device name and not definition 4) Operations provided listed "#" numbers that correlate to device numbers listed within test report 60066583. 5) Updated table in annex as a duplicate of the table within the DoC.	J. Strong	2015-05-21
E	Since cuffs (no bladder) are CE marked for the entire device (cuff & bladder), the following cuffs (no bladder) material numbers are being added back onto this DoC: 5082-01, 5082-01H, 5082-02, 5082-11, 5082-16, 5082-21, 5082-24. Since descriptions have been included in table in the main declaration of conformity, the table in the annex isn't needed, so that data has been removed.	M. McGovern	2016-01-08

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F	Updated for MDR	C. Lefancheck	2020-03-23
G	Class I updates for MDR	C. Lefancheck	2021-06-15
H	DoC Correction & SRN	K. Love	2021-08-20
J	DoC Correction, New SAP Change Number	K. Love	2021-08-23
K	Updated to new template, added SRN for Skaneateles and updated the part number list to a table format.	K. Ockenfels	2021-10-12
L	Updated to new template, added Intended Purpose Statement	K. Love	2021-11-08
M	Updated part list to remove the -SC cuffs which are now classified as Kits due to small bore compliance	K Ockenfels	2022-02-04
N	Add EN ISO 14971:2019, EN ISO 20417:2021. Update DoC expiration date to align with EN ISO 13485 certificate.	K. Love	2022-12-02
P	Added product description for all listed product codes	M. Solanki	2024-05-10