

## DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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
<b>EC REP</b>	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name <sup>1,3</sup> :	Welch Allyn FlexiPort™ Blood Pressure Cuffs
<b>REF</b> <sub>1,3</sub>	901043 BLOOD PRESSURE CUFF, REUSEABLE 901044 BLOOD PRESSURE CUFF, DISPOSABLE
<b>#</b> <sub>1,3</sub>	Refer to Table (below)

Welch Allyn FlexiPort™ Blood Pressure Cuffs – REUSE Series	
<b>#</b>	<b>Description</b>
REUSE-06	CUFF, WA, REUSABLE, SMALL INFA
REUSE-06-1HP	CUFF, REUS, SM INFANT, 1-TUBE,
REUSE-06-1MQ	CUFF, REUS, SM INFANT, 1-TUBE,
REUSE-06-1SC	CUFF, REUS, SM INFANT, 1-TUBE,
REUSE-06-1TP	CUFF, REUS, SM INFANT, 1-TUBE,
REUSE-06-1TPE	CUFF, REUS, SM INFANT, 1-TUBE
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-07-1SC	CUFF, REUS, INFANT, 1-TUBE, SC
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, BV
REUSE-07-2MF	CUFF, REUS, INFANT, 2-TUBE, MF
REUSE-07-2MQ	CUFF, REUS, INFANT, 2-TUBE, MQ
REUSE-07-2SC	CUFF, REUS, INFANT, 2-TUBE, SC
REUSE-07-2TP	CUFF, REUS, INFANT, 2-TUBE, TP

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC  
<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU  
<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – REUSE Series	
#	Description
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-08-1TPE	CUFF, REUS SM CHILD 1-TUBE TPE
REUSE-08-2BV	CUFF, REUS SM CHILD 2-TUBE, BV
REUSE-08-2BVC	CUFF, REUS SM CHILD 2-TUBE, BV
REUSE-08-2MF	CUFF, REUS SM CHILD 2-TUBE MF
REUSE-08-2MQ	CUFF, REUS SM CHILD 2-TUBE, MQ
REUSE-08-2SC	CUFF, REUS SM CHILD 2-TUBE, SC
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-09-1SC	CUFF, REUS, CHILD, 1-TUBE, SC
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-09-2SC	CUFF, REUS, CHILD, 2-TUBE, SC
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-10-1SC	CUFF, REUS, SM AD, 1-TUBE, SC
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-10-2SC	CUFF, REUS, SM AD, 2-TUBE, SC
REUSE-10-2TP	CUFF, REUS, SM AD, 2-TUBE, TP
REUSE-10-2TPE	CUFF, REUS, SM AD, 2-TUBE, TPE

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC  
<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU  
<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – REUSE Series	
#	Description
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-11-1SC	CUFF, REUS, ADULT, 1-TUBE, SC
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-11-2SC	CUFF, REUS, ADULT, 2-TUBE, SC
REUSE-11-2TP	CUFF, REUS, ADULT, 2-TUBE, TP
REUSE-11-2TPE	CUFF, REUS, ADULT, 2-TUBE, TPE
REUSE-11C	REUSE-11 NIBP CUFF FOR CHINA
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-1SC	CUFF, REUS, AD LONG 1-TUBE, SC
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, BV
REUSE-11L-2MF	CUFF, REUS, AD LONG 2-TUBE, MF
REUSE-11L-2MQ	CUFF, REUS, AD LONG 2-TUBE, MQ
REUSE-11L-2SC	CUFF, REUS, AD LONG 2-TUBE, SC
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-12-1SC	REUS, LG AD, 1-TUBE, SC
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-12-2SC	CUFF, REUS, LG AD, 2-TUBE, SC
REUSE-12-2TP	CUFF, REUS, LG AD, 2-TUBE, TP
REUSE-12-2TPE	CUFF, REUS, LG AD, 2-TUBE, TPE

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – REUSE Series	
#	Description
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-1SC	CUFF REUS LG AD LONG 1-TUBE SC
REUSE-12L-1TP	CUFF REUS LG AD LONG 1-TUBE TP
REUSE-12L-1TPE	CUFF REUS LG AD LONG 1-TUBE TP
REUSE-12L-2BV	CUFF REUS LG AD LONG 2-TUBE BV
REUSE-12L-2BVC	CUFF REUS LG AD LONG 2-TUBE BV
REUSE-12L-2MF	CUFF REUS LG AD LONG 2-TUBE MF
REUSE-12L-2MQ	CUFF REUS LG AD LONG 2-TUBE MQ
REUSE-12L-2SC	CUFF REUS LG AD LONG 2-TUBE SC
REUSE-12L-2TP	CUFF REUS LG AD LONG 2-TUBE TP
REUSE-12L-2TPE	CUFF REUS LG AD LONG 2-TUBE TP
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-13-1SC	CUFF, REUS, THIGH, 1-TUBE, SC
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
REUSE-13-2SC	CUFF, REUS, THIGH, 2-TUBE, SC
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,THI
REUSE-FP-BV	CUFF, REUSE, FP WALL PACK
REUSE-FP-HAND	CUFF, REUSE, FP HAND GAUGE PAC
REUSE-FP-MON	CUFF,REUSE, FP MONITOR PACK
REUSE-MLT	CUFF, REUS, MULTIPACK
REUSE-MLT-1	CUFF,REUSE,ADULT MULTIPACK,1-T
REUSE-MLT-2	CUFF,REUSE,ADULT MULTIPACK,2-T
REUSE-PED-BV	CUFF, REUSE, PED WALL PACK
REUSE-PED-HAND	CUFF, REUSE, PED HAND GAUGE PA
REUSE-PED-MON	CUFF, REUSE, PED MONITOR PACK
405190	CUFF, REUSE, AD + LG AD, 1TB S
405192	CUFF, REUSE, AD + LG AD, 2TB M
405240	CUFF, REUSE,CHILD,AD,LG AD, 1T
405242	CUFF,REUSE,CHILD,AD,LGAD,THIGH

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – REUSE Series	
#	Description
405260	CUFF, REUSE, CHILD, 2-TUBE, TP
410519	CUFF KIT
412942	CUFF KIT, PHYSICIANS OFFICE

Welch Allyn FlexiPort™ Blood Pressure Cuffs – SOFT Series	
#	Description
SOFT-06	CUFF, WA, SOFT, SMALL INFANT
SOFT-06-1HP	CUFF, SOFT, SM INFANT, 1-TUBE,
SOFT-06-1MQ	CUFF, SOFT, SM INFANT, 1-TUBE,
SOFT-06-1SC	CUFF, SOFT, SM INFANT, 1-TUBE,
SOFT-06-1TP	CUFF, SOFT, SM INFANT, 1-TUBE,
SOFT-06-1TPE	CUFF, SOFT, SM INFANT, 1-TUBE,
SOFT-07	CUFF, WA, SOFT, INFANT
SOFT-07-1HP	CUFF, SOFT, INFANT, 1-TUBE, HP
SOFT-07-1MQ	CUFF, SOFT, INFANT, 1-TUBE, MQ
SOFT-07-1SC	CUFF, SOFT, INFANT, 1-TUBE, SC
SOFT-07-1TP	CUFF, SOFT, INFANT, 1-TUBE, TP
SOFT-07-1TPE	CUFF, SOFT, INFANT, 1-TUBE, TP
SOFT-07-2BV	CUFF, SOFT, INFANT, 2-TUBE, BV
SOFT-07-2BVC	CUFF, SOFT, INFANT, 2-TUBE, BV
SOFT-07-2MF	CUFF, SOFT, INFANT, 2-TUBE, MF
SOFT-07-2MQ	CUFF, SOFT, INFANT, 2-TUBE, MQ
SOFT-07-2SC	CUFF, SOFT, INFANT, 2-TUBE, SC
SOFT-07-2TP	CUFF, SOFT, INFANT, 2-TUBE, TP
SOFT-07-2TPE	CUFF, SOFT, INFANT, 2-TUBE TPE
SOFT-08	CUFF, WA, SOFT, SMALL CHILD
SOFT-08-1HP	CUFF, SOFT SM CHILD 1-TUBE, HP
SOFT-08-1MQ	CUFF, SOFT SM CHILD 1-TUBE, MQ
SOFT-08-1SC	CUFF, SOFT SM CHILD 1-TUBE, SC
SOFT-08-1TP	CUFF, SOFT SM CHILD 1-TUBE, TP
SOFT-08-1TPE	CUFF, SOFT, SM CHILD 1-TUBE, T
SOFT-08-2BV	CUFF, SOFT SM CHILD 2-TUBE, BV
SOFT-08-2BVC	CUFF, SOFT SM CHILD 2-TUBE, BV
SOFT-08-2MF	CUFF, SOFT, SM CHILD, 2-TUBE,
SOFT-08-2MQ	CUFF, SOFT SM CHILD 2-TUBE, MQ
SOFT-08-2SC	CUFF, SOFT SM CHILD 2-TUBE, SC
SOFT-08-2TP	CUFF, SOFT SM CHILD 2-TUBE, TP
SOFT-08-2TPE	CUFF, SOFT SM CHILD 2-TUBE TPE
SOFT-09	CUFF, WA, SOFT, CHILD
SOFT-09-1HP	CUFF, SOFT, CHILD, 1-TUBE, HP

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – SOFT Series	
#	Description
SOFT-09-1MQ	CUFF, SOFT, CHILD, 1-TUBE, MQ
SOFT-09-1SC	CUFF, SOFT, CHILD, 1-TUBE, SC
SOFT-09-1TP	CUFF, SOFT, CHILD, 1-TUBE, TP
SOFT-09-1TPE	CUFF, SOFT, CHILD, 1-TUBE, TPE
SOFT-09-2BV	CUFF, SOFT, CHILD, 2-TUBE, BV
SOFT-09-2BVC	CUFF, SOFT, CHILD, 2-TUBE, BVC
SOFT-09-2MF	CUFF, SOFT, CHILD, 2-TUBE, MF
SOFT-09-2MQ	CUFF, SOFT, CHILD, 2-TUBE, MQ
SOFT-09-2SC	CUFF, SOFT, CHILD, 2-TUBE, SC
SOFT-09-2SCC	CUFF, SOFT, CHILD, 2-TUBE, SCC
SOFT-09-2TP	CUFF, SOFT, CHILD, 2-TUBE, TP
SOFT-09-2TPE	CUFF, SOFT, CHILD, 2-TUBE, TPE
SOFT-10	CUFF, WA, SOFT, SMALL ADULT
SOFT-10-1HP	CUFF, SOFT, SM AD, 1-TUBE, HP
SOFT-10-1MQ	CUFF, SOFT, SM AD, 1-TUBE, MQ
SOFT-10-1SC	CUFF, SOFT, SM AD, 1-TUBE, SC
SOFT-10-1TP	CUFF, SOFT, SM AD, 1-TUBE, TP
SOFT-10-1TPE	CUFF, SOFT, SM AD, 1-TUBE, TPE
SOFT-10-2BV	CUFF, SOFT, SM AD, 2-TUBE, BV
SOFT-10-2BVC	CUFF, SOFT, SM AD, 2-TUBE, BVC
SOFT-10-2MF	CUFF, SOFT, SM AD, 2-TUBE, MF
SOFT-10-2MQ	CUFF, SOFT, SM AD, 2-TUBE, MQ
SOFT-10-2SC	CUFF, SOFT, SM AD, 2-TUBE, SC
SOFT-10-2SCC	CUFF SOFT SM ADULT 2-TUBE, SCC
SOFT-10-2TP	CUFF, SOFT, SM AD, 2-TUBE, TP
SOFT-10-2TPE	CUFF, SOFT, SM AD, 2-TUBE, TPE
SOFT-11	CUFF, WA, SOFT, ADULT
SOFT-11-1HP	CUFF, SOFT, ADULT, 1-TUBE, HP
SOFT-11-1MQ	CUFF, SOFT, ADULT, 1-TUBE, MQ
SOFT-11-1SC	CUFF, SOFT, ADULT, 1-TUBE, SC
SOFT-11-1TP	CUFF, SOFT, ADULT, 1-TUBE, TP
SOFT-11-1TPE	CUFF, SOFT, ADULT, 1-TUBE, TPE
SOFT-11-2BV	CUFF, SOFT, ADULT, 2-TUBE, BV
SOFT-11-2BVC	CUFF, SOFT, ADULT, 2-TUBE, BVC
SOFT-11-2MF	CUFF, SOFT, ADULT, 2-TUBE, MF
SOFT-11-2MQ	CUFF, SOFT, ADULT, 2-TUBE, MQ
SOFT-11-2SC	CUFF, SOFT, ADULT, 2-TUBE, SC
SOFT-11-2SCC	CUFF, SOFT, ADULT, 2-TUBE, SCC
SOFT-11-2TP	CUFF, SOFT, ADULT, 2-TUBE, TP
SOFT-11-2TPE	CUFF, SOFT, ADULT, 2-TUBE, TPE

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – SOFT Series	
#	Description
SOFT-11L	CUFF, WA, SOFT, ADULT LONG
SOFT-11L-1HP	CUFF, SOFT, AD LONG 1-TUBE, HP
SOFT-11L-1MQ	CUFF, SOFT, AD LONG 1-TUBE, MQ
SOFT-11L-1SC	CUFF, SOFT, AD LONG 1-TUBE, SC
SOFT-11L-1TP	CUFF, SOFT, AD LONG 1-TUBE, TP
SOFT-11L-1TPE	CUFF, SOFT, AD LONG, 1-TUBE, T
SOFT-11L-2BV	CUFF, SOFT, AD LONG 2-TUBE, BV
SOFT-11L-2BVC	CUFF, SOFT, AD LONG 2-TUBE, BV
SOFT-11L-2MF	CUFF, SOFT, AD LONG, 2-TUBE, M
SOFT-11L-2MQ	CUFF, SOFT, AD LONG 2-TUBE, MQ
SOFT-11L-2SC	CUFF, SOFT, AD LONG 2-TUBE, SC
SOFT-11L-2TP	CUFF, SOFT, AD LONG 2-TUBE, TP
SOFT-11L-2TPE	CUFF, SOFT, AD LONG 2-TUBE TPE
SOFT-12	CUFF, WA, SOFT, LG ADULT
SOFT-12-1HP	CUFF, SOFT, LG AD, 1-TUBE, HP
SOFT-12-1MQ	CUFF, SOFT, LG AD, 1-TUBE, MQ
SOFT-12-1SC	CUFF, SOFT, LG AD, 1-TUBE, SC
SOFT-12-1TP	CUFF, SOFT, LG AD, 1-TUBE, TP
SOFT-12-1TPE	CUFF, SOFT, LG AD, 1-TUBE, TPE
SOFT-12-2BV	CUFF, SOFT, LG AD, 2-TUBE, BV
SOFT-12-2BVC	CUFF, SOFT, LG AD, 2-TUBE, BVC
SOFT-12-2MF	CUFF, SOFT, LG AD, 2-TUBE, MF
SOFT-12-2MQ	CUFF, SOFT, LG AD, 2-TUBE, MQ
SOFT-12-2SC	CUFF, SOFT, LG AD, 2-TUBE, SC
SOFT-12-2SCC	CUFF, SOFT, LG AD, 2-TUBE, SCC
SOFT-12-2TP	CUFF, SOFT, LG AD, 2-TUBE, TP
SOFT-12-2TPE	CUFF, SOFT, LG AD, 2-TUBE, TPE
SOFT-12L	CUFF, WA, SOFT, LG ADULT LONG
SOFT-12L-1HP	CUFF SOFT LG AD LONG 1-TUBE HP
SOFT-12L-1MQ	CUFF SOFT LG AD LONG 1-TUBE MQ
SOFT-12L-1SC	CUFF SOFT LG AD LONG 1-TUBE SC
SOFT-12L-1TP	CUFF SOFT LG AD LONG 1-TUBE TP
SOFT-12L-1TPE	CUFF, SOFT, LG AD LONG, 1-TUBE
SOFT-12L-2BV	CUFF SOFT LG AD LONG 2-TUBE BV
SOFT-12L-2BVC	CUFF SOFT LG AD LONG 2-TUBE BV
SOFT-12L-2MF	CUFF, SOFT, LG AD LONG, 2-TU
SOFT-12L-2MQ	CUFF SOFT LG AD LONG 2-TUBE MQ
SOFT-12L-2SC	CUFF SOFT LG AD LONG 2-TUBE SC
SOFT-12L-2TP	CUFF SOFT LG AD LONG 2-TUBE TP
SOFT-12L-2TPE	CUFF SOFT LGAD LONG 2-TUBE TPE

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

<b>Welch Allyn FlexiPort™ Blood Pressure Cuffs – SOFT Series</b>	
<b>#</b>	<b>Description</b>
SOFT-13	CUFF, WA, SOFT, THIGH
SOFT-13-1HP	CUFF, SOFT, THIGH, 1-TUBE, HP
SOFT-13-1MQ	CUFF, SOFT, THIGH, 1-TUBE, MQ
SOFT-13-1SC	CUFF, SOFT, THIGH, 1-TUBE, SC
SOFT-13-1TP	CUFF, SOFT, THIGH, 1-TUBE, TP
SOFT-13-1TPE	CUFF, SOFT, THIGH, 1-TUBE, TPE
SOFT-13-2BV	CUFF, SOFT, THIGH, 2-TUBE, BV
SOFT-13-2BVC	CUFF, SOFT, THIGH, 2-TUBE, BVC
SOFT-13-2MF	CUFF, SOFT, THIGH, 2-TUBE, MF
SOFT-13-2MQ	CUFF, SOFT, THIGH, 2-TUBE, MQ
SOFT-13-2SC	CUFF, SOFT, THIGH, 2-TUBE, SC
SOFT-13-2SCC	CUFF, SOFT, THIGH, 2-TUBE, SCC
SOFT-13-2TP	CUFF, SOFT, THIGH, 2-TUBE, TP
SOFT-13-2TPE	CUFF, SOFT, THIGH, 2-TUBE, TPE
SOFT-MLT	CUFF, SOFT, MULTIPACK
SOFT-MLT-1	CUFF,SOFT,ADULT MULTIPACK,1-TB
SOFT-MLT-2	CUFF,SOFT,ADULT MULTIPACK,2-TB
VSOFT-09	NOVAPLUS RAW CUFF SOFT CHILD
VSOFT-10	NOVAPLUS RAW CUFF SOFT SMALL A
VSOFT-11	NOVAPLUS RAW CUFF SOFT ADULT
VSOFT-11L	NOVAPLUS RAW CUFF SOFT ADULT L
VSOFT-12	NOVAPLUS RAW CUFF SOFT LG ADUL
VSOFT-12L	NOVAPLUS RAW CUFF SOFT LG ADUL

<b>Welch Allyn FlexiPort™ Blood Pressure Cuffs – VINYL Series</b>	
<b>#</b>	<b>Description</b>
VINYL-06	CUFF, WA, VINYL, SMALL INFANT
VINYL-06-1HP	CUFF, VINYL SM INFANT, 1-TUBE,
VINYL-06-1MQ	CUFF, VINYL SM INFANT, 1-TUBE,
VINYL-06-1SC	CUFF, VINYL SM INFANT, 1-TUBE,
VINYL-07	CUFF, WA, VINYL INFANT
VINYL-07-1HP	CUFF, VINYL INFANT, 1-TUBE, HP
VINYL-07-1MQ	CUFF, VINYL INFANT, 1-TUBE, MQ
VINYL-07-1SC	CUFF, VINYL INFANT, 1-TUBE, SC
VINYL-07-2BV	CUFF, VINYL INFANT, 2-TUBE, BV
VINYL-07-2BVC	CUFF, VINYL INFANT, 2-TUBE, BV
VINYL-07-2MQ	CUFF, VINYL INFANT, 2-TUBE, MQ
VINYL-07-2SC	CUFF, VINYL INFANT, 2-TUBE, SC
VINYL-08	CUFF, WA, VINYL SM CHILD
VINYL-08-1HP	CUFF, VINYL SM CHILD 1-TUBE HP

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU



Welch Allyn FlexiPort™ Blood Pressure Cuffs – VINYL Series	
#	Description
VINYL-08-1MQ	CUFF, VINYL SM CHILD 1-TUBE MQ
VINYL-08-1SC	CUFF, VINYL SM CHILD 1-TUBE SC
VINYL-08-2BV	CUFF, VINYL SM CHILD 2-TUBE BV
VINYL-08-2BVC	CUFF, VINYL SM CHILD 2-TUBE BV
VINYL-08-2MQ	CUFF, VINYL SM CHILD 2-TUBE MQ
VINYL-08-2SC	CUFF, VINYL SM CHILD 2-TUBE SC
VINYL-09	CUFF, WA, VINYL CHILD
VINYL-09-1HP	CUFF, VINYL CHILD, 1-TUBE, HP
VINYL-09-1MQ	CUFF, VINYL CHILD, 1-TUBE, MQ
VINYL-09-1SC	CUFF, VINYL CHILD, 1-TUBE, SC
VINYL-09-2BV	CUFF, VINYL CHILD, 2-TUBE, BV
VINYL-09-2BVC	CUFF, VINYL CHILD, 2-TUBE, BVC
VINYL-09-2MQ	CUFF, VINYL CHILD, 2-TUBE, MQ
VINYL-09-2SC	CUFF, VINYL CHILD, 2-TUBE, SC
VINYL-10	CUFF, WA, VINYL, SM AD
VINYL-10-1HP	CUFF, VINYL, SM AD, 1-TUBE, HP
VINYL-10-1MQ	CUFF, VINYL, SM AD, 1-TUBE, MQ
VINYL-10-1SC	CUFF, VINYL, SM AD, 1-TUBE, SC
VINYL-10-2BV	CUFF, VINYL, SM AD, 2-TUBE, BV
VINYL-10-2BVC	CUFF, VINYL, SM AD, 2-TUBE, BV
VINYL-10-2MQ	CUFF, VINYL, SM AD, 2-TUBE, MQ
VINYL-10-2SC	CUFF, VINYL, SM AD, 2-TUBE, SC
VINYL-11	CUFF, WA, VINYL ADULT
VINYL-11-1HP	CUFF, VINYL ADULT, 1-TUBE, HP
VINYL-11-1MQ	CUFF, VINYL ADULT, 1-TUBE, MQ
VINYL-11-1SC	CUFF, VINYL ADULT, 1-TUBE, SC
VINYL-11-2BV	CUFF, VINYL ADULT, 2-TUBE, BV
VINYL-11-2BVC	CUFF, VINYL ADULT, 2-TUBE, BVC
VINYL-11-2MQ	CUFF, VINYL ADULT, 2-TUBE, MQ
VINYL-11-2SC	CUFF, VINYL ADULT, 2-TUBE, SC
VINYL-11L	CUFF, WA, VINYL, ADULT LONG
VINYL-11L-1HP	CUFF, VINYL AD LONG 1-TUBE, HP
VINYL-11L-1MQ	CUFF, VINYL AD LONG 1-TUBE, MQ
VINYL-11L-1SC	CUFF, VINYL AD LONG 1-TUBE, SC
VINYL-11L-2BV	CUFF, VINYL AD LONG 2-TUBE, BV
VINYL-11L-2BVC	CUFF, VINYL AD LONG 2-TUBE, BV
VINYL-11L-2MQ	CUFF, VINYL AD LONG 2-TUBE, MQ
VINYL-11L-2SC	CUFF, VINYL AD LONG 2-TUBE, SC
VINYL-12	CUFF, WA, VINYL LG AD
VINYL-12-1HP	CUFF, VINYL LG AD, 1-TUBE, HP

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Welch Allyn FlexiPort™ Blood Pressure Cuffs – VINYL Series	
#	Description
VINYL-12-1MQ	CUFF, VINYL LG AD, 1-TUBE, MQ
VINYL-12-1SC	CUFF, VINYL LG AD, 1-TUBE, SC
VINYL-12-2BV	CUFF, VINYL LG AD, 2-TUBE, BV
VINYL-12-2BVC	CUFF, VINYL LG AD, 2-TUBE, BVC
VINYL-12-2MQ	CUFF, VINYL LG AD, 2-TUBE, MQ
VINYL-12-2SC	CUFF, VINYL LG AD, 2-TUBE, SC
VINYL-12L	CUFF, WA, VINYL, LG ADULT LONG
VINYL-12L-1HP	CUFF VINYL LG AD LONG 1-TUBE H
VINYL-12L-1MQ	CUFF VINYL LG AD LONG 1-TUBE M
VINYL-12L-1SC	CUFF VINYL LG AD LONG 1-TUBE S
VINYL-12L-2BV	CUFF VINYL LG AD LONG 2-TUBE B
VINYL-12L-2BVC	CUFF VINYL LG AD LONG 2-TUBE B
VINYL-12L-2MQ	CUFF VINYL LG AD LONG 2-TUBE M
VINYL-12L-2SC	CUFF VINYL LG AD LONG 2-TUBE S
VINYL-13	CUFF, WA, VINYL THIGH
VINYL-13-1HP	CUFF, VINYL THIGH, 1-TUBE, HP
VINYL-13-1MQ	CUFF, VINYL THIGH, 1-TUBE, MQ
VINYL-13-1SC	CUFF, VINYL THIGH, 1-TUBE, SC
VINYL-13-2BV	CUFF, VINYL THIGH, 2-TUBE, BV
VINYL-13-2BVC	CUFF, VINYL THIGH, 2-TUBE, BVC
VINYL-13-2MQ	CUFF, VINYL THIGH, 2-TUBE, MQ
VINYL-13-2SC	CUFF, VINYL THIGH, 2-TUBE, SC
VINYL-MLT	CUFF, VINYL, MULTIPACK

Radio equipment<sup>2</sup>: Not applicable, no radio

Object of the declaration<sup>2</sup>: Not applicable, no radio

Accessories and components<sup>2</sup>: Not applicable, no radio

Medical Device Conformity Assessment Route Annex<sup>1</sup>: VII

Medical Device Classification<sup>1</sup>: I

Medical Device Classification Rules<sup>1</sup>: 1

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

GMDN Code and Term <sup>1</sup> :	34978 Cuff, blood pressure, reusable	
UMDNS Code and Term <sup>1</sup> :	11072 Cuffs	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	EN/ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
	EN/ISO 81060-1	Non-invasive sphygmomanometers- Part 1: Requirements and test methods for non-automated measurement type.
	EN/ISO 80369-5	Small-bore connectors for liquids and gases in healthcare applications – Part 5: Connectors for limb cuff inflation applications Note: FlexiPort blood pressure cuffs supplied without connectors have an inner-fluid pathway diameter greater than 8.5 mm and, therefore, are not subject to this standard. This includes: SOFT-06 through SOFT-13 (including -11L and -12L) VINYL-06 through VINYL-13 (including -11L and -12L) REUSE-06 through REUSE-13 (including -11L and -12L) For FlexiPort cuffs shipped with connectors, the part numbers ending in -1HP include a bayonet connector that complies with this standard.

Authorised Signatory:



Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

2019-07-18

Date

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Place of Issue

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU