EU Declaration of Conformity (DoC)

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EU DoC ID	*80016679 Version U*
Manufacturer Name and Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA Manufacturer Single Registration Number (SRN): US-MF-000013394
Authorised Representative	Name and Address: Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland
Authorized Representative Single Registration Number (SRN)	IE-AR-000000768

+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++

Other relevant Directives, Regulations and Union Legislations that the device is in conformity with: N/A

Common Specifications Applied: N/A

Product/Trade Name and Product Code or REF. number: 901043 BLOOD PRESSURE CUFF, REUSABLE

Product Code	Product Name
EUSE-R06	CUFF, WA, REUSABLE, SMALL INFANT
REUSE-06-1HP	CUFF, REUS, SM INFANT, 1-TUBE, HP

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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-08-1TPE	CUFF, REUS SM CHILD 1-TUBE TPE
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

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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

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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
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
412942	CUFF KIT, PHYSICIAN'S OFFICE

Intended Purpose/Use: Welch Allyn FlexiPort Reusable 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.
FlexiPort blood pressure cuffs are intended to be used by a clinically trained, medical professional.

Device Risk Class: Class I

Product Basic UDI-DI Number: 0732094GMN901043EY

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MDR EU Certificate(s) No.: N/A
Conformity Assessment Description/Annexes: Annex II and Annex III, Rule 1
Notified Body Name and Address: N/A

+++ This Declaration is made on the following basis:
• For devices with a MDR EU Certificate issued by a Notified Body:
  o The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.
  o The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.
• For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature.
• Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
• Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Authorised Signatory:	
Name and Title:	Joseph Olsavsky, Sr. Director Regulatory Affairs
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA
Date of Issue:	May 21, 2026
Signature:	**Signature:** JOSEPH OLSAVSKY Electronically signed by: JOSEPH OLSAVSKY Reason: I approve this document Date: May 21, 2026 10:30:41 EDT **Email:** joseph_olsavsky@baxter.com