

**WelchAllyn®** **DECLARATION OF CONFORMITY**  
 (in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016679

Version: E

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 Two-Piece Blood Pressure Cuffs

**REF**

901043 BLOOD PRESSURE CUFF, REUSEABLE

**#**

<b>Welch Allyn Two-Piece</b>	
<b>#</b>	<b>Description</b>
4500-02	CUFF & BAG, ADULT, 2 T MONITOR
4500-03	CUFF & BAG, LG ADULT, 2 T MNTR
45-15-389	CHLD CUF -PRIMUS68,PSTABIL3,IS
45-22-189	ADULT ARM CUFF FOR PRIMUS 68 A
45-23-189	LARGE ADULT ARM CUFF FOR PRIMU
47-15-389	CHILD VELCRO CUFF, 9X18, 2-TUB
47-22-189	ADULT ARM CUFF FOR MAXI STABIL
47-23-189	LARGE ADULT ARM CUFF FOR MAXI
5082-01	CUFF, ADULT
5082-01H	CUFF, ADULT, HOSPITAL PACK
5082-02	CUFF, CHILD
5082-03	CUFF, INFANT W/1 TUBE BAG
5082-07	CUFF, NEWBORN, W/1 TUBE BAG
5082-08	CUFF, INFANT W/2 TUBE BAG
5082-11	CUFF, THIGH
5082-144	CUFF & BAG, NEWBORN, 2 TUBE
5082-16	CUFF, LARGE ADULT
5082-21	INF SYST, CHILD CUFF
5082-22	INF SYST, ADULT CUFF
5082-22H	INF SYST, ADULT, HOSPITAL PACK

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<b>#</b>	<b>Description</b>
5082-23	INF SYST, LARGE ADULT CUFF
5082-23H	INF SYST, LG ADULT HOSPITAL PK
5082-24	CUFF, CHILD W/2 TUBE BAG
5082-25	CUFF, ADULT W/2 TUBE BAG
5082-26	CUFF, LARGE ADULT W/2 TUBE BAG
5082-42	CUFF, CHILD W/1 TUBE BAG
5082-43	CUFF, ADULT W/1 TUBE BAG
5082-44	CUFF, LARGE ADULT W/1 TUBE BAG
5082-45	INF SYST, THIGH CUFF
5082-65	CUFF, THIGH W/1 TUBE BAG
5082-77	CUFF, THIGH W/1 TUBE BAG
5082-78	CUFF, THIGH W/2 TUBE BAG
5200-01	CUFF, ADULT, W/6 IN TUBE
5200-02	CUFF, LARGE ADULT, W/6 IN TUBE
97S155N-515A	BAG,ADULT,GRAY,1 TUBE

Annex: VII

Classification: I

Classification 1

Rules:

GMDN Code and Term: 34978-Cuff, blood pressure, reusable


UMDNS Code and Term: 11072 Cuffs

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Standards Applied:	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.

Authorised Signatory:

  
Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

2016-01-11  
Date

Navan  
Place of Issue