

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

#

Welch Allyn Two-Piece	
#	Description
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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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