

SAP DIR No.:

80016527

Version:

B

We declare, under our sole responsibility, that the product listed below conforms to the provisions of 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 Ltd.
Navan Business Park
Dublin Road
Navan, County Meath
Republic of Ireland

Product Name: FlexiPort™ Blood Pressure Cuffs

REF **Reuse-X where X corresponds to the following extensions:** 06, 06-1HP, 06-1MQ, 06-1SC, 06-1TP, 06-1TPE,
07, 07-1HP, 07-1ML, 07-1MQ, 07-1SC, 07-1TP, 07-1TPE, 07-2BV, 07-2BVC, 07-2MF, 07-2MQ, 07-2SC, 07-2TP, 07-2TPE,
08, 08-1HP, 08-1MQ, 08-1SC, 08-1TP, 08-1TPE, 08-2BV, 08-2BVC, 08-2MF, 08-2MQ, 08-2SC, 08-2TP, 08-2TPE,
09, 09-1HP, 09-1MQ, 09-1SC, 09-1TP, 09-1TPE, 09-2BV, 09-2BVC, 09-2MF, 09-2MQ, 09-2SC, 09-2TP, 09-2TPE,
10, 10-1HP, 10-1MQ, 10-1SC, 10-1TP, 10-1TPE, 10-2BV, 10-2BVC, 10-2MF, 10-2MQ, 10-2SC, 10-2TP, 10-2TPE,
11, 11-1HP, 11-1MQ, 11-1SC, 11-1TP, 11-1TPE, 11-2BV, 11-2BVC, 11-2MF, 11-2MQ, 11-2SC, 11-2TP, 11-2TPE,
11L, 11L-1HP, 11L-1MQ, 11L-1SC, 11L-1TP, 11L-1TPE, 11L-2BV, 11L-2BVC, 11L-2MF, 11L-2MQ, 11L-2SC, 11L-2TP, 11L-2TPE,
12, 12-1HP, 12-1MQ, 12-1SC, 12-1TP, 12-1TPE, 12-2BV, 12-2BVC, 12-2MF, 12-2MQ, 12-2SC, 12-2TP, 12-2TPE,
12L, 12L-1HP, 12L-1MQ, 12L-1SC, 12L-1TP, 12L-1TPE, 12L-2BV, 12L-2BVC, 12L-2MF, 12L-2MQ, 12L-2SC, 12L-2TP, 12L-2TPE,
13, 13-1HP, 13-1MQ,
13-1SC, 13-1TP, 13-1TPE, 13-2BV, 13-2BVC, 13-2MF, 13-2MQ, 13-2SC, 13-2TP, 13-2TPE,
MLT, MLT-1, MLT-2;
Soft-X where X corresponds to the following extensions: 06, 06-1HP, 06-1MQ, 06-1SC, 06-1TP, 06-1TPE,

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	<p>07, 07-1HP, 07-1MQ, 07-1SC, 07-1TP, 07-1TPE, 07-2BV, 07-2BVC, 07-2MF, 07-2MQ, 07-2SC, 07-2TP, 07-2TPE,</p> <p>08, 08-1HP, 08-1MQ, 08-1SC, 08-1TP, 08-1TPE, 08-2BV, 08-2BVC, 08-2MF, 08-2MQ, 08-2SC, 08-2TP, 08-2TPE,</p> <p>09, 09-1HP, 09-1MQ, 09-1SC, 09-1TP, 09-1TPE, 09-2BV, 09-2BVC, 09-2MF, 09-2MQ, 09-2SC, 09-2SCC, 09-2TP, 09-2TPE,</p> <p>10, 10-1HP, 10-1MQ, 10-1SC, 10-1TP, 10-1TPE, 10-2BV, 10-2BVC, 10-2MF, 10-2MQ, 10-2SC, 10-2SCC, 10-2TP, 10-2TPE,</p> <p>11, 11-1HP, 11-1MQ, 11-1SC, 11-1TP, 11-1TPE, 11-2BV, 11-2BVC, 11-2MF, 11-2MQ, 11-2SC, 11-2SCC, 11-2TP, 11-2TPE,</p> <p>11L, 11L-1HP, 11L-1MQ, 11L-1SC, 11L-1TP, 11L-1TPE, 11L-2BV, 11L-2BVC, 11L-2MF, 11L-2MQ, 11L-2SC, 11L-2TP, 11L-2TPE,</p> <p>12, 12-1HP, 12-1MQ, 12-1SC, 12-1TP, 12-1TPE, 12-2BV, 12-2BVC, 12-2MF, 12-2MQ, 12-2SC, 12-2SCC, 12-2TP, 12-2TPE,</p> <p>12L, 12L-1HP, 12L-1MQ, 12L-1SC, 12L-1TP, 12L-1TPE, 12L-2BV, 12L-2BVC, 12L-2MF, 12L-2MQ, 12L-2SC, 12L-2TP, 12L-2TPE,</p> <p>13, 13-1HP, 13-1MQ, 13-1SC, 13-1TP, 13-1TPE, 13-2BV, 13-2BVC, 13-2MF, 13-2MQ, 13-2SC, 13-2SCC, 13-2TP, 13-2TPE,</p> <p>MLT, MLT-1, MLT-2;</p> <p>Vinyl-X where X corresponds to the following extensions: 06, 06-1HP, 06-1MQ, 06-1SC, 07, 07-1HP, 07-1MQ, 07-1SC, 07-2BV, 07-2BVC, 07-2MQ, 07-2SC, 08, 08-1HP, 08-1MQ, 08-1SC, 08-2BV, 08-2BVC, 08-2MQ, 08-2SC, 09, 09-1HP, 09-1MQ, 09-1SC, 09-2BV, 09-2BVC, 09-2MQ, 09-2SC, 10, 10-1HP, 10-1MQ, 10-1SC, 10-2BV, 10-2BVC, 10-2MQ, 10-2SC, 11, 11-1HP, 11-1MQ, 11-1SC, 11-2BV, 11-2BVC, 11-2MQ, 11-2SC, 11L, 11L-1HP, 11L-1MQ, 11L-1SC, 11L-2BV, 11L-2BVC, 11L-2MQ, 11L-2SC, 12, 12-1HP, 12-1MQ, 12-1SC, 12-2BV, 12-2BVC, 12-2MQ, 12-2SC, 12L, 12L-1HP, 12L-1MQ, 12L-1SC, 12L-2BV, 12L-2BVC, 12L-2MQ, 12L-2SC, 13, 13-1HP, 13-1MQ, 13-1SC, 13-2BV, 13-2BVC, 13-2MQ, 13-2SC,</p> <p>MLT;</p> <p>DS44-DURX, where X corresponds to the following extensions: 09, 09F, 09P, 09PF, 10, 10F, 11, 11F, 12, 12F;</p> <p>DS45-DURX, where X corresponds to the following extensions: 09, 09F, 09P, 09PF, 10, 10F, 11, 11F, 12, 12F;</p>
Annex:	VII
Classification:	I
Classification Rules:	1

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GMDN Code and Term:	34978-Cuff, blood pressure, reusable	
UMDNS Code and Term	11072 bandlike devices encircling a body part or another device. Cuffs used in medical procedures or monitoring are typically filled with air or fluid.	
Standards Applied:	ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
	EN 1060-1	Non-Invasive Sphygmomanometers – Part 1: General Requirements
	EN 1060-2	Non-Invasive Sphygmomanometers – Part 2: Supplementary Requirements for Mechanical Sphygmomanometers
	EN 1060-3	Non-Invasive Sphygmomanometers – Part 3: Supplementary Requirements for Electro-Mechanical Blood Pressure Measuring Systems
	ISO 81060-1	Non-invasive sphygmomanometers- Part 1: Requirements and test methods for non-automated measurement type.

Authorised Signatory:



Kevin Crossen, Regulatory Affairs Representative

2013-1-14

Date