

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

SAP DIR No.: 80016654      Version: F

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



Regulatory Affairs Representative  
Welch Allyn Limited  
Navan Business Park  
Dublin Road  
Navan, County Meath  
Republic of Ireland

Product Name: Welch Allyn Neonate Blood Pressure Cuffs



901044 BLOOD PRESSURE CUFF, DISPOSABLE



NEO-1-1, NEO-1-2, NEO-1-2CL, NEO-2-1, NEO-2-2, NEO-2-2CL, NEO-3-1, NEO-3-2, NEO-3-2CL, NEO-4-1, NEO-4-2, NEO-4-2CL, NEO-5-1, NEO-5-2, NEO-5-2CL, NEO-MLT-1, NEO-MLT-2

Annex: VII

Classification: I

Classification: 1

Rules:

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

UMDNS Code and Term: 11072 Cuffs

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

SAP DIR No.: 80016654      Version: F

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

2015-10-16  
Date

Navan  
Place of Issue