DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Document Number 80029129	Version D	
Product Name	Two-Piece Blood Pressure Cuffs	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
Declaration of Conformity Validity	ISO 13485 #314505 MP2016 Expiry Date: 2024-11-07	
EC REP	Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland	SRN: IE-AR-000000768
Object of the declaration	 Two Piece Blood Pressure Cuffs	
Intended Purpose	Welch Allyn Pediatric through Adult 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.	
Medical Device Conformity Assessment Route Annex	Annex II and Annex III	
Medical Device Classification	Class I	
Medical Device Classification Rule	Rule I	
Standards	Refer to Appendix A	

REF #	901043: Blood Pressure Cuff, Reusable
	4500-02
	4500-03
	5200-01
	5200-02
	5082-01
	5082-02
	5082-03
	5082-07
	5082-08
	5082-11
	5082-16
	5082-21
	5082-22
	5082-23
	5082-24
	5082-25
	5082-26
	5082-42
	5082-43
	5082-44
	5082-45
	5082-77
	5082-78
	45-15-389
	45-22-189
	45-23-189
	47-15-389
	47-22-189
	47-23-189
GMDN Code and Term	34978 - Blood Pressure Cuff, Reusable
UMDNS Code and Term	11072 - Cuffs
Basic UDI-DI	0732094GMN901043EY

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Approval

DocuSigned by:
Katherine Love
Signer Name: Katherine Love
Signing Reason: I approve this document
Signing Time: December 8, 2022 | 9:55:08 AM EST
BB8F4DB0044F42B2B2541C9071BCB69A

December 8, 2022 | 11:24:01 AM EST

Katherine Love
Principal Specialist, Regulatory Affairs

Date

Skaneateles Falls, NY USA
Place of Issue

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Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 15223-1	2016	Medical Devices - Symbols to be Used with medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements
	EN ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing
	EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	EN ISO 81060-1	2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non- automated measurement type
	EN 80369-5	2016	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications
	EN 62366-1	2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices

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Document Change History

Version	Description	Author	Date
A	Initial Version. This DoC supersedes previous 2-Piece Cuff DoC DIR 80016679 which now contains Flexiport Reusable Cuffs only.	K Ockenfels	2021-09-30
B	Added Intended Purpose statement and removed 14971 standard, not needed.	K Ockenfels	2021-11-18
C	Removed Bladder only part numbers, due not contain a CE Mark accessories only. Removed 7052-35 and 7052-36 per marketing products will move to OB.	K Ockenfels	2022-01-5
D	DoC expiration date to align with EN ISO 13485 certificate.	D. Sharma	2022-12-07