Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.
Welch Allyn, Inc
4341 State Street Road
SKANEATELES FALLS NY 13153

80029538 VER. B

DECLARATION OF CONFORMITY

We, Welch Allyn, Inc., as the Product Owner, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the ASEAN Agreement on Medical Device Directive.

Name and Address of Product Owner:
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153

Name and Address of Physical Manufacturer:

1. Welch Allyn, Inc., 4341 State Street Road, Skaneateles Falls, NY 13153
2. Welch Allyn de Mexico S. de R.L. de C.V., Calle Emilio Flores 2471-A, Colonia Canon del Padre, 22203 Tijuana, BC, Mexico
3. Better Enterprises Co., Ltd. No 101, Moudan Lane, Lugang Township, Changhua County 50545, Taiwan, ROC

Name and Address of Authorized Representative:
Modernform Health & Care Public Co., Ltd
699 Modernform Tower, Srinakarindr Rd., Pattanakarn, Suanluang, Bangkok 10250

Medical Device(s):

Welch Allyn Spot Vital Signs 4400
Product code: 44XT-B, 44WT-B
Accessories list: According to the attachment (Annex I)

Risk Classification: e.g. Class B, rule
Class 3, Rule 10(1)

Quality Management System Certificate:
Certification Body: DQS Medizinprodukte GmbH
Certificate Number: 314505 MP2016
Issue Date: 2019-12-09
Expiry Date: 2022-12-08
QMS Standard: EN ISO 13485:2016

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Standards Applied:

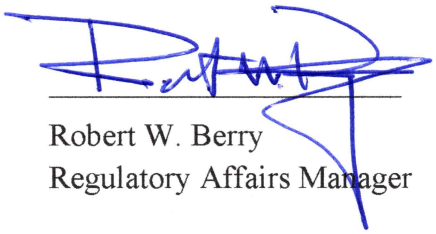
Standards Applied	Version/Date of Issue	Title
EN 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	2014	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
EN/IEC 60601-1-6	2013	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
EN ISO 81060-2	2014	Non-invasive sphygmomanometers_-Part_2: Clinical validation of automated measurement type
EN ISO 80601-2-30	2018	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 80601-2-56	2018	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 80601-2-61	2017	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 62366-1	2015	Medical devices -- Part 1: Application of usability engineering to medical devices
EN 62304	2015	Medical Device Software – Software Life Cycle Processes

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Standards Applied	Version/Date of Issue	Title
EN ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 62321-1	2013	Determination of certain substances in electrotechnical products – Part 1: Introduction and overview
EN ISO 13485	2018	Medical devices - Quality management systems - Requirements for regulatory purposes

This declaration of conformity is valid from 2022-04-28

Authorized Signatory:



Robert W. Berry
Regulatory Affairs Manager

2022-04-28
Date

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Annex I: Accessories List

Part Number	Part Description
4400-DST	Spot 4400 Desk Stand
02895-000	PROBE WELL KIT OEM ORAL 9'
ECOCUFF-09	ECOCUFF, CHILD, 15-21 CM
4400-MBS	4400 MOBILE STAND
4400-PS	SPOT 4400 35 WATT POWER SUPPLY
02894-1000	ASSY,PRB WLL,RED,OEM,M690_692
02895-100	PROBE WELL KIT OEM RECTAL 9'
ECOCUFF-12	ECOCUFF, LARGE ADULT, 33-45 CM
BATT22	CONNEX SPOT, 2 CELL LI-ION BATTERY
PWCD-B	LINE CORD B, NORTH AMERICA
REUSE-11L	CUFF, WA, REUSABLE ADULT LONG
SOFT-12	CUFF, WA, SOFT, LG ADULT
SOFT-13	CUFF, WA, SOFT, THIGH
ECOCUFF-10	ECOCUFF, SMALL ADULT, 20-28 CM
ECOCUFF-11	ECOCUFF, ADULT, 27-38 CM
SOFT-09	CUFF, WA, SOFT, CHILD
02894-0000	ASSY, PRB WLL,BLUE,OEM,M690_692
REUSE-10	CUFF, WA, REUSABLE, SM ADULT
REUSE-07	CUFF, WA, REUSABLE, INFANT
REUSE-09	CUFF, WA, REUSABLE, CHILD

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Part Number	Part Description
SOFT-11L	CUFF, WA, SOFT, ADULT LONG
SOFT-12L	CUFF, WA, SOFT, LG ADULT LONG
44XT-B	SPOT 4400 WITH NIBP AND SURETEMP PLUG B
REUSE-11	CUFF, WA, REUSABLE, ADULT
REUSE-12	CUFF, WA, REUSABLE, LG ADULT
44WT-B	SPOT 4400 W NIBP SURETEMP NONIN PLUG B
SOFT-08	CUFF, WA, SOFT, SMALL CHILD
06138-000	CAL-KEY, ASSY, M690/692
REUSE-13	CUFF, WA, REUSABLE, THIGH
REUSE-06	CUFF, WA, REUSABLE, SMALL INFANT
REUSE-08	CUFF, WA, REUSABLE, SM CHILD
REUSE-12L	CUFF, WA, REUS, LG ADULT LONG
SOFT-11	CUFF, WA, SOFT, ADULT
4500-34	FAST BP HOSE W FPORT, 5 FT
4500-35	FAST BP HOSE W FPORT, 10 FT
106275	USB cable for wired connectivity
5082-166	Plastic male luer slip connector, 5/32" with barbed end (Pack of 10)
5082-170	Plastic connector for 5/32" I.D. tubing (Pack of 10)
5082-148	Y-tubing with two metal screw type hose connectors, and one metal beyonet connector
5082-171	Plastic connector for 1/8" to 5/32" I.D. tubing (Pack of 10)

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Part Number	Part Description
5082-177	Bayonet adapter
5082-184	Bayonet connector
5082-149	Y-tubing with two metal screw type hose connectors with no fitting on end
5082-176	Plastic male luer slip connector (neonatal use) for 3/32 I.D. tubing (Pack of 10)
5082-246	Monitor tubing, 3 meters
5082-244	Monitor tubing, 3 meters
5082-245	Monitor tubing, 3 meters
5082-183	Y-tubing adaptor with no fittings (Pack of 10)
5082-185	Bayonet adapter for use
5082-175	Plastic screw-type hose adapter w/barbed end for 1/8" I.D. tubing (Pack of 10)
5082-164	Plastic screw type connector with female Luer on screw end and barbed opposite end (Pack of 10)
5082-174	Plastic screw-type hose adapter w/barbed end for 5/32" I.D. tubing (Pack of 10)
5082-165	Plastic male locking luer with barbed end (Pack of 10)
1-BARB	BP Port Fitting, 1-Tube, Barbs, (Pack of 10)
1-HP	BP Port Fitting, 1-Tube, Bayonet, (Pack of 10)
1-MQ	BP Port Fitting, 1-Tube, Locking, (Pack of 10)
1-TPL	BP Port Fitting, 1-Tube, Tri-Purpose, (Pack of 10)
2-SRC	BP Port Fitting, 2-Tube, For SRC, (Pack of 10)
2-BVLC	BP Port Fitting, 2-Tube, Large bulb, valve and clamp, (Pack of 10)
2-MF	BP Port Fitting, 2 Tube, M/F Locking, (Pack of 10)
2-SC	BP Port Fitting, 2-Tube, Screw, (Pack of 10)

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Part Number	Part Description
2-TP	BP Port Fitting, 2-Tube, Tri-Purpose, (Pack of 10)
2-BARB	BP Port Fitting, 2-Tube, Barbs, (Pack of 10)
2-BVL	BP Port Fitting, 2-Tube, Large bulb and value, (Pack of 10)
2-BVD	BP Port Fitting, 2-Tube, Economic bulb, (Pack of 10)
2-SCC	BP Port Fitting, 2-Tube, Screw & Clamp, (Pack of 10)
PORT-2	BP FlexiPort Fitting, 2-Tube, (Pack of 10)
PORT-1	BP FlexiPort Fitting, 1-Tube, (Pack of 10)
5082-188	FlexiPort Tubing, 8", (Pack of 10)
5082-189	FlexiPort Tubing, 13", (Pack of 10)
5082-159	Wash Cap, FlexiPort BP Cuff, (EA)
01802-110	9600 Plus Calibration Tester
REUSE-11-1HP	Cuff, Adult, Durable, 1-Tube, HP
REUSE-06-1HP	Cuff, Small Infant, Durable, 1-Tube, HP
REUSE-11L-1HP	Cuff, Adult Long, Durable, 1-Tube, HP
REUSE-10-1HP	Cuff, Small Adult, Durable, 1-Tube, HP
REUSE-12-1HP	Cuff, Large Adult, Durable, 1-Tube, HP
REUSE-12L-1HP	Cuff, Large Adult Long, Durable, 1-Tube, HP
REUSE-13-1HP	Cuff, Thigh, Durable, 1-Tube, HP
REUSE-07-1HP	Cuff, Infant, Durable, 1-Tube, HP
REUSE-08-1HP	Cuff, Small Child, Durable, 1-Tube, HP
REUSE-09-1HP	Cuff, Child, Durable, 1-Tube, HP

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Part Number	Part Description
REUSE-11L-1MQ	Cuff, Adult Long, Durable, 1-Tube, Locking
REUSE-12-1MQ	Cuff, Large Adult, Durable, 1-Tube, Locking
REUSE-13-1MQ	Cuff, Thigh, Durable, 1-Tube, Locking
REUSE-06-1MQ	Cuff, Small Infant, Durable, 1-Tube, Locking
REUSE-08-1MQ	Cuff, Small Child, Durable, 1-Tube, Locking
REUSE-09-1MQ	Cuff, Child, Durable, 1-Tuble, Locking
REUSE-12L-1MQ	Cuff, Large Adult Long, Durable, 1-Tube, Locking
REUSE-07-1MQ	Cuff, Infant, Durable, 1-Tube, Locking
REUSE-11-1MQ	Cuff, Adult, Durable, 1-Tube, Locking
REUSE-10-1MQ	Cuff, Small Adult, Durable, 1-Tube, Locking
REUSE-09-1SC	Cuff, Child, Durable, 1-Tube, Screw
REUSE-10-1SC	Cuff, Small Adult, Durable, 1-Tube, Screw
REUSE-13-1SC	Cuff, Thigh, Durable, 1-Tube, Screw
REUSE-06-1SC	Cuff, Small Infant, Durable, 1-Tube, Screw
REUSE-12L-1SC	Cuff, Large Adult Long, Durable, 1-tube, Screw
REUSE-11L-1SC	Cuff, Adult Long, Durable, 1 Tube, Screw
REUSE-08-1SC	Cuff, Small Child, Durable, 1-Tube, Screw
REUSE-12-1SC	Cuff, Large Adult, Durable, 1-Tube, Screw
REUSE-07-1SC	Cuff, Infant, Durable, 1-Tube, Screw
REUSE-11-1SC	Cuff, Adult, Durable, 1-Tube, Screw
REUSE-06-1TP	Cuff, Small Infant, Durable, 1-Tube, TP

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Part Number	Part Description
REUSE-10-1TP	Cuff, Small Adult, Durable, 1-Tube, TP
REUSE-11-1TP	Cuff, Adult, Durable, 1-Tube, TP
REUSE-12-1TP	Cuff, Large Adult, Durable, 1-Tube, TP
REUSE-11L-1TP	Cuff, Adult Long, Durable, 1-Tube, TP
REUSE-12L-1TP	Cuff, Large Adult Long, Durable, 1-Tube, TP
REUSE-07-1TP	Cuff, Infant, Durable, 1-Tube, TP
REUSE-09-1TP	Cuff, Child, Durable, 1-Tube, TP
REUSE-08-1TP	Cuff, Small Child, Durable, 1-Tube, TP
REUSE-13-1TP	Cuff, Thigh, Durable, 1-Tube, TP
REUSE-07-2TP	Cuff, Infant, Durable, 2-Tube, TP
REUSE-11L-2TP	Cuff, Adult Long, Durable, 2-Tube, TP
REUSE-11-2TP	Cuff, Adult, Durable, 2-Tube, TP
REUSE-12-2TP	Cuff, Large Adult, Durable, 2-Tube, TP
REUSE-08-2TP	Cuff, Small Child, Durable, 2-Tube, TP
REUSE-09-2TP	Cuff, Child, Durable, 2-Tube, TP
REUSE-10-2TP	Cuff, Small Adult, Durable, 2-Tube, TP
REUSE-12L-2TP	Cuff, Large Adult Long, Durable, 2-Tube, TP
REUSE-13-2TP	Cuff, Thigh, Durable, 2-Tube, TP
REUSE-11L-2MQ	Cuff, Adult Long, Durable, 2-Tube, Locking
REUSE-08-2MQ	Cuff, Small Child, Durable, 2-Tube, Locking
REUSE-11-2MQ	Cuff, Adult, Durable, 2-Tube, Locking

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Part Number	Part Description
REUSE-12-2MQ	Cuff, Large Adult, Durable, 2-Tube, Locking
REUSE-07-2MQ	Cuff, Infant, Durable, 2-Tube, Locking
REUSE-09-2MQ	Cuff, Child, Durable, 2-Tube, Locking
REUSE-10-2MQ	Cuff, Small Adult, Durable, 2-Tube, Locking
REUSE-12L-2MQ	Cuff, Large Adult Long, Durable, 2-Tube, Locking
REUSE-13-2MQ	Cuff, Thigh, Durable, 2-Tube, Locking
REUSE-11-2SC	Cuff, Adult, Durable, 2-Tube, Screw
REUSE-10-2SC	Cuff, Small Adult, Durable, 2-Tube, Screw
REUSE-08-2SC	Cuff, Small Child, Durable, 2-Tube, Screw
REUSE-09-2SC	Cuff, Child, Durable, 2-Tube, Screw
REUSE-07-2SC	Cuff, Infant, Durable, 2-Tube, Screw
REUSE-13-2SC	Cuff, Thigh, Durable, 2-Tube, Screw
REUSE-11L-2SC	Cuff, Adult Long, Durable, 2-Tube, Screw
REUSE-12L-2SC	Cuff, Large Adult Long, Durable, 2-Tube, Screw
REUSE-12-2SC	Cuff, Large Adult, Durable, 2-Tube, Screw
SOFT-10-1HP	Cuff, Small Adult, Disposable, 1-Tube, HP
SOFT-12-2TP	Cuff, Large Adult, Disposable, 2-Tube, TP
SOFT-12-2MQ	CUFF, SOFT, LG AD, 2-TUBE, MQ
SOFT-13-2MQ	CUFF, SOFT, THIGH, 2-TUBE, MQ
SOFT-11L-1SC	Cuff, Adult Long, Disposable, 1-Tube, Screw
SOFT-11-1TP	Cuff, Adult, Disposable, 1-Tube, TP

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Part Number	Part Description
SOFT-13-1TP	Cuff, Thigh, Disposable, 1-Tube, TP
SOFT-07-2MQ	CUFF, SOFT, INFANT, 2-TUBE, MQ
SOFT-06-1MQ	Cuff, Small Infant, Disposable, 1-Tube, Locking
SOFT-09-1SC	Cuff, Child, Disposable, 1-Tube, Screw
SOFT-11-1HP	Cuff, Adult, Disposable, 1-Tube, HP
SOFT-13-1HP	Cuff, Thigh, Disposable, 1-Tube, HP
SOFT-12L-1SC	Cuff, Large Adult Long, Disposable, 1-Tube, Screw
SOFT-08-1TP	Cuff, Small Child, Disposable, 1-Tube, TP
SOFT-07-1HP	Cuff, Infant, Disposable, 1-Tube, HP
SOFT-11-1MQ	Cuff, Adult, Disposable, 1-Tube, Locking
SOFT-08-2MQ	CUFF, SOFT SM CHILD 2-TUBE, MQ
SOFT-07-1TP	Cuff, Infant, Disposable, 1-Tube, TP
SOFT-08-1HP	Cuff, Small Child, Disposable, 1-Tube, HP
SOFT-12-1HP	Cuff, Large Adult, Disposable, 1-Tube, HP
SOFT-12L-1TP	Cuff, Large Adult Long, Disposable, 1-Tube, TP
SOFT-11-2MQ	CUFF, SOFT, ADULT, 2-TUBE, MQ
SOFT-11L-1HP	Cuff, Adult Long, Disposable, 1-Tube, HP
SOFT-09-1MQ	Cuff, Child, Disposable, 1-Tube, Locking
SOFT-06-1TP	Cuff, Small Infant, Disposable, 1-Tube, TP
SOFT-08-1MQ	Cuff, Smalll Child, Disposable, 1-Tube, Locking
SOFT-11-2TP	Cuff, Adult, Disposable, 2-Tube, TP

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Part Number	Part Description
SOFT-12-1MQ	Cuff, Large Adult, Disposable, 1-Tube, Locking
SOFT-13-1MQ	Cuff, Thigh, Disposable, 1-Tube, Locking
SOFT-12L-2TP	Cuff, Large Adult Long, Disposable, 2-Tube, TP
SOFT-11L-2TP	Cuff, Adult Long, Disposable, 2-Tube, TP
SOFT-06	Cuff, Small Infant, Disposable
SOFT-10-1MQ	Cuff, Small Adult, Disposable, 1-Tube, Locking
SOFT-10-1SC	Cuff, Small Adult, Disposable, 1-Tube, Screw
SOFT-12-1TP	Cuff, Large Adult, Disposable, 1-Tube, TP
SOFT-08-2TP	Cuff, Small Child, Disposable, 2-Tube, TP
SOFT-09-2TP	Cuff, Child, Disposable, 2-Tube, TP
SOFT-10-2MQ	CUFF, SOFT, SM AD, 2-TUBE, MQ
SOFT-09-1HP	Cuff, Child, Disposable, 1-Tube, HP
SOFT-12L-1MQ	Cuff, Large Adult Long, Disposable, 1-Tube, Locking
SOFT-12-1SC	Cuff, Large Adult, Disposable, 1-Tube, Screw
SOFT-13-1SC	Cuff, Thigh, Disposable, 1-Tube, Screw
SOFT-11L-2MQ	CUFF, SOFT, AD LONG 2-TUBE, MQ
SOFT-06-1HP	Cuff, Small Infant, Disposable, 1-Tube, HP
SOFT-12L-1HP	Cuff, Large Adult Long, Disposable
SOFT-11L-1MQ	Cuff, Adult Long, Disposable, Soft, 1-Tube, Locking
SOFT-12L-2MQ	CUFF SOFT LG AD LONG 2-TUBE MQ
SOFT-10	Cuff, Small Adult, Disposable

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Part Number	Part Description
SOFT-06-1SC	Cuff, Small Infant, Disposable, 1-Tube, Screw
SOFT-08-1SC	Cuff, Small Child, Disposable, 1-Tube, Screw
SOFT-11-1SC	Cuff, Adult, Disposable, 1-Tube, Screw
SOFT-11L-1TP	Cuff, Adult Long, Disposable, 1-Tube, TP
SOFT-07-2TP	Cuff, Infant, Disposable, 2-Tube, TP
SOFT-07-1MQ	Cuff, Infant, Disposable, 1-Tube, Locking
SOFT-07-1SC	Cuff, Infant, Disposable, 1-Tube, Screw
SOFT-09-1TP	Cuff, Child, Disposable, 1-Tube, TP
SOFT-10-1TP	Cuff, Small Adult, Disposable, 1-Tube, TP
SOFT-10-2TP	Cuff, Small Adult, Disposable, 2-Tube, TP
SOFT-07	Cuff, Infant, Disposable
SOFT-13-2TP	Cuff, Thigh, Disposable, 2-Tube, TP
SOFT-09-2MQ	CUFF, SOFT, CHILD, 2-TUBE, MQ
VINYL-10-2MQ	CUFF, VINYL, SM AD, 2-TUBE, MQ
VINYL-11L-2MQ	CUFF, VINYL AD LONG 2-TUBE, MQ
VINYL-07-2MQ	CUFF, VINYL INFANT, 2-TUBE, MQ
VINYL-11-2MQ	CUFF, VINYL ADULT, 2-TUBE, MQ
VINYL-09	CUFF, WA, VINYL CHILD
VINYL-11	CUFF, WA, VINYL ADULT
VINYL-08	CUFF, WA, VINYL SM CHILD
VINYL-10	CUFF, WA, VINYL, SM AD

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Part Number	Part Description
VINYL-06	CUFF, WA, VINYL, SMALL INFANT
VINYL-07	CUFF, WA, VINYL INFANT
VINYL-08-2MQ	CUFF, VINYL SM CHILD 2-TUBE MQ
VINYL-11L	CUFF, WA, VINYL, ADULT LONG
VINYL-09-2MQ	CUFF, VINYL CHILD, 2-TUBE, MQ