



Welch Allyn, Inc. is a subsidiary of Baxter International, Inc.

**80029663 VER. D**

## **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 Medical Device Regulations in Thailand according to the Medical Device Act B.E. 2551 (2008) and the amended Medical Device Act B.E. 2562 (2019), 2nd edition.

### **Name and Address of Product Owner:**

Welch Allyn, Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153 USA

### **Name and Address of Physical Manufacturer:**

1. Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153
2. Better Enterprises Co., Ltd. No 101, Moudan Lane, Lugang Township, Changhua County 50545, Taiwan, ROC
3. THERMOFORM ENGINEERED QUALITY, LLC (TEQ), 11287 Kiley Drive, Huntley, IL 60142 United States
4. Welch Allyn de Mexico S.de R.L. de C.V., Calle Emilio Flores 2471-A, Col. Cañon del Padre, Tijuana, Baja California, CP 22230 Mexico

### **Name and Address of Authorized Representative:**

MD Healthcare Co., Ltd.  
14/51-53 Moo 15, Bang Kaeo Subdistrict, Bang Phli District, Samutprakarn 10540, Thailand

### **Medical Device(s):**

Welch Allyn® Connex® Spot Monitor – Refer to Annex A for full list of products

### **Risk Classification: e.g. Class B, rule**

Class 3, Rule 10(1)



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### **Quality Management System Certificate:**

#### **Welch Allyn, Inc.**

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

#### **Welch Allyn de Mexico S. de R.L. de C.V.**

Certification Body: DQS Medizinprodukte GmbH

Certificate Number: 375038 MP2016

Issue Date: 2021-10-18

Expiry Date: 2024-10-17

QMS Standard: EN ISO 13485:2016

#### **TEQ**

Certification Body: Perry Johnson Registrars, Inc.

Certificate Number: C2019-04269

Issue Date: 2019-12-16

Expiry Date: 2022-12-07

QMS Standard: EN ISO 13485:2016

#### **Better Enterprise**

Certification Body: BSI

Certificate Number: MD 597728

Issue Date: 2022-05-07

Expiry Date: 2025-05-06

QMS Standard: EN ISO 13485:2016

**Standards Applied:**

<b>Number</b>	<b>Version/Date of Issue</b>	<b>Title</b>
EN 60601-1	2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	2015	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
EN 60601-1-6	2015	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
EN 60601-1-8	2017	Medical Electrical Equipment – Part 1-8: General Requirements for Safety – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
EN ISO 60601-2-49	2015	Medical electrical equipment_ - Part_2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
EN ISO 81060-2	2014	Non-Invasive Sphygmomanometers – Clinical investigation of automated measurement type.
EN ISO 80601-2-30	2019	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



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Number	Version/Date of Issue	Title
EN 62133-2	2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
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
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 1060-3	2009	Non-Invasive Sphygmomanometers – Part 3. Supplementary Requirements for Electro-Mechanical Blood Pressure Measuring Systems
EN ISO 15223-1	2021	Medical devices_ - Symbols to be used with medical device labels, labelling and information to be supplied_ - Part_1: General requirements
EN ISO 14971	2019/A11:2021	Medical devices_ - Application of risk management to medical devices
EN ISO 13485	2020	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

This declaration of conformity is valid from Date: 2022-09-19

Authorized Signatory:

Beth Rice

Name: Beth Rice

Date: 2022-09-19

Position: RA Engineer



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**Annex A:**

<b>Part Number</b>	<b>Device name</b>
71WE-B	VALUE CSM,NIBP,SpO2,BRAUNPRO6000,PLUGB
71WT-B	VALUE CSM,NIBP,SpO2,SURETEMP,PLUGB
71WX-B	VALUE CSM,NIBP,SpO2,PLUGB
71XE-B	VALUECSM,NIBP,BRAUNPRO6000,PLUGB
71XT-B	VALUE CSM,NIBP,SURETEMP,PLUGB
71XX-B	VALUE CSM,NIBP,PLUGB
73CE-B	BT CSM,NIBP,COVIDIEN,BRAUNPRO6000,PLUGB
73CT-B	BT CSM,NIBP,COVIDIEN,SURETEMP,PLUGB
73ME-B	BT CSM,NIBP,MASIMO,BRAUNPRO6000,PLUGB
73MT-B	BT CSM,NIBP,MASIMO,SURETEMP,PLUGB
73RT-B	BT,CSM,NIBP,Mas,RRP,SureTemp,Plug B
73RE-B	BT,CSM,NIBP,Mas,Resp Rate,Braun Pro6000,Plug B
75CE-B	WIFI CSM,NIBP,COVIDIEN,BRAUN6000,PLUGB
75CT-B	WIFI CSM,NIBP,COVIDIEN, SURETEMP,PLUGB
75ME-B	WIFI CSM,NIBP,MASIMO,BRAUN PRO6000,PLUGB
75MT-B	WIFI,CSM,NIBP,MASIMO,SURETEMP,PLUGB
75RE-B	WIFI,CSM,NIBP,Mas,RRp,Braun Pro6000,Plug B
75RT-B	WIFI,CSM,NIBP,Mas,RRp,SureTemp,Plug B
4500-34	FAST BP HOSE W FPORT, 5 FT
4500-35	FAST BP HOSE W FPORT, 10 FT
6083-001	UNI-EXT-1 1m Sensor Extension Cable
6083-003	UNI-EXT-3 3m Sensor Extension Cable
7000-33	NEONATAL BLOOD PRESSURE HOSE (10ft)
7000-916HSR	JADAK BARCODE/RFID READER
7000-APM	CONNEX SPOT ACCY POWER MGMT STAND
7000-BOX	Connex Spot Packaging (Empty Box Set)
7000-GCX	Connex Spot GCX VESA Wall Mount
7000-HOLSTER	HOLSTER KIT
7000-MS3	Connex Spot Classic Mobile Stand MS3
7000-MWS	CONNEX SPOT MOBILE WORK STAND
7000-PS	Connex Spot 35 Watt Power Supply
7426-001	6000CA ADULT CLOTH DISPOSABLE 24/BX
7426-002	6000CP PEDIATRIC CLOTH DISPOSABLE 24/BX
7426-003	6000CI INFANT CLOTH DISPOSABLE 24/BX
7426-004	6000CN NEONATE CLOTH DISPOSABLE 24/BOX
BATT22	CONNEX SPOT, 2 CELL LI-ION BATTERY
6000-30	1SINGLE TUBE BLOOD PRESSURE HOSE (5 FT)



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<b>Part Number</b>	<b>Device name</b>
7000-DST	CSM Desk Stand
6000-31	Single tube blood pressure hose (10 ft)
106275	USB cable for wired connectivity
PWCD-B	Line cord B
PWCD-2	Line cord 2
6000-NC	Nurse call cable
7000-916HS	Jadak 2D Scanner
660-0321-00	Patch cable, 50'
660-0320-00	Patch cable, 100'
660-0138-00	Patch cable, 5'
6000-50	VSM 6000 USB Configuration Memory Stick
4600-90E	BP Accuracy, Variability Card
06000-801	Braun ThermoScan Pro6000 Disposable Probe Covers PC800
06000-800	Disposable probe covers (800 covers, packaged 200/box)
06000-005	Braun ThermoScan Pro6000 Disposable Probe Covers PC 5K
104894	Rechargeable Battery
02895-000	Oral probe and well kit (9ft. / 2.7M)
02895-100	Rectal probe and well kit (9ft. 2.7M)
02894-0000	Oral probe well (blue)
02894-1000	Rectal probe well (red)
06138-000	Temperature calibration key
01802-110	9600 Plus Calibration Tester
REUSE-06	Cuff, Small Infant, Durable
REUSE-07	Cuff, Infant, Durable
REUSE-13	Cuff, Thigh, Durable
SOFT-08	Cuff, Small Child, Disposable
SOFT-09	Cuff, Child, Disposable
SOFT-11	Cuff, Adult, Disposable
SOFT-12	Cuff, Large Adult, Disposable
SOFT-10	Cuff, Small Adult, Disposable
SOFT-11L	Cuff, Adult Long, Disposable
SOFT-13	Cuff, Thigh, Disposable
SOFT-12L	Cuff, Large Adult Long, Disposable
NEO-2-1	Monitor Cuff Neonate #2, 1-tube (10 per box)
NEO-5-1	Monitor Cuff Neonate #5, 1-tube (10 per box)
NEO-4-1	Monitor Cuff Neonate #4, 1-tube (10 per box)
NEO-3-1	Monitor Cuff Neonate #3, 1-tube (10 per box)
NEO-1-1	Monitor Cuff Neonate #1, 1-tube (10 per box)
05031-101	SureTemp Plus Disposable probe covers (1,000 covers, packaged 25/box)



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<b>Part Number</b>	<b>Device name</b>
ECOCUFF-MLT	50 Each of Child, Small Adult, Adult and Large Adult Cuffs (200/Case)
05031-110	SureTemp Plus Disposable probe covers (10,000 covers, packaged 25/box)
ECOCUFF-12	Large Adult, 33-45 cm (100/Case)
ECOCUFF-11	Adult, 27-38 cm (100/Case)
ECOCUFF-10	Small Adult, 20-28 cm (100/Case)
ECOCUFF-09	Child, 15-21 cm (100/Case)
106201	Pro 6000 tether w/6 ft cord
106204	Pro 6000 tether w/9 ft cord