Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

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Legal Manufacturer Name: Welch Allyn, Inc.

Legal Manufacturer Address: 4341 State Street Road, Skaneateles Falls, NY 13153, USA

Legal Manufacturer Single Registration Number (SRN): US-MF-00013394

Authorised Representative Name (if applicable): Welch Allyn Limited

Authorised Representative Address: Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22

Authorised Representative Single Registration Number (SRN): IE-AR-000000768

Notified Body Name and Address:

DQS Medizinprodukte GmbH

August-Schanze-Straße 21, 60433 Frankfurt am Main

Notified Body Identification Number: 0297

MDD Certificate Number: 314505 MR2

Original expiry date as indicated on the MDD Certificate prior to the extension of the validity:

May 26, 2024

End date of extended validity/transition period [1]: December 31, 2028

[1] according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).

+++ We, as the legal manufacturer declare under our sole responsibility:

- for the above listed **MDD Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions: +++

This declaration is made on the following basis:

1. The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.
2. The device(s) continue to comply with Directive 93/42/EEC (MDD)
3. The device does not undergo a significant change in the design and intended purpose from 26 May 2021.

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4. The device(s) do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

5. Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

6. A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) is put in place by the manufacturer no later than 26 May 2024.

7. A formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made to the notified body for the device(s) listed on this declaration or has been made in respect of a device intended to substitute a device listed on this declaration, no later than 26 May 2024 and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) no later than 26 September 2024.

Product/Trade Name and Product Code or REF. number:

- Braun ThermoScan PRO 6000 Ear Thermometer
- SureTemp Plus Clinical Electronic Thermometers and Accessories
- ProBP3400 Digital Blood Pressure Device

See Appendix A for Product Codes.

Device MDR Risk Class: All devices listed above are Class IIa

Authorised Signatory:	
Name and Title:	Joseph Olsavsky
Function	PRRC
Place of Issue:	4341 State Street Road, Skaneateles Falls, NY 13153, USA
Date of Issue:	14-Feb-2024
Signature:	JOSEPH OLSAVSKY *Electronically signed by: JOSEPH OLSAVSKY Reason: I approve this document Date: Feb 14, 2024 11:46 EST*

Legal Manufacturer's Declaration

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Appendix A: List of medical devices from MDD DoC or PCL

Product Code or REF number	Product or Trade Name
Braun ThermoScan PRO 6000 Ear Thermometer	
06000-200	PRO 6000 W/SMALL CRADLE
06000-300	PRO 6000 W/LARGE CRADLE
SureTemp Plus Clinical Electronic Thermometers and Accessories	
01690-401	PCK THERM SYS, M690, INTL 4' RE
01690-410	PKG THERM, M690, INTL, 4', OR
01690-501	PKG THERM SYS, M690, INTL 9FT RE
01692-400	PKG THERM INTL, M692, 4', OR
01692-401	PKG THERM SYS, M692, INTL 4' RE
01692-500	PKG THERM SYS, M692, INTL 9FT OR
01692-501	PKG THERM SYS, M692, INTL 9FT RE
02892-000	PROBE WELL KIT 4FT, RECTAL
02892-100	PROBE WELL KIT 9FT, RECTAL
02893-000	PROBE WELL KIT 4FT, ORAL
02893-100	PROBE WELL KIT 9FT, ORAL
02895-000	PROBE WELL KIT OEM ORAL 9'
02895-100	PROBE WELL KIT OEM RECTAL 9'
02678-000	PROBE ASSY, LATHG CONN, ORAL, 4FT
02678-100	PROBE ASSY, LATHG CONN, ORAL, 9FT

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02679-000	PROBE ASSY, LATHG CONN, RCTL, 4FT
02679-100	PROBE ASSY, LATHG CONN, RCTL, 9FT
PROBP 3400 Digital Blood Pressure Device	
34XF	PROBP 3400 SUREBP, UNIT ONLY
34XF-EX	PROBP 3400 STANDARD W/SUREBP EXCHANGE
34XFHT-2	PROBP 3400, SUREBP, HANDHELD, EU
34XFHT-4	PROBP 3400, SUREBP, HANDHELD, UK
34XFHT-6	PROBP 3400, SUREBP, HANDHELD, AU
34XFHT-B	PROBP 3400, SUREBP, WALL
34XFST-2	PROBP 3400, SUREBP, MOBILE, EU
34XFST-4	PROBP 3400, SUREBP, MOBILE, UK
34XFST-6	PROBP 3400, SUREBP, MOBILE, AU
34XFST-B	PROBP 3400, SUREBP, MOBILE
34XFWT-2	PROBP 3400, SUREBP, WALL, EU
34XFWT-4	PROBP 3400, SUREBP, WALL, UK
34XFWT-6	PROBP 3400, SUREBP, WALL, AU
34XFWT-B	PROBP 3400, SUREBP, WALL
34XX	PROBP 3400 STANDARD, UNIT ONLY
34XX-EX	PROBP 3400 STANDARD EXCHANGE
34XXHT-2	PROBP 3400, HANDHELD, EU
34XXHT-4	PROBP 3400, HANDHELD, UK
34XXHT-6	PROBP 3400, HANDHELD, AU
34XXHT-B	PROBP 3400, HANDHELD, NA

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34XXST-2	PROBP 3400, MOBILE, EU
34XXST-4	PROBP 3400, MOBILE, UK
34XXST-6	PROBP 3400, MOBILE, AU
34XXST-B	PROBP 3400, MOBILE, NA
34XXWT-2	PROBP 3400, WALL, EU
34XXWT-4	PROBP 3400, WALL, UK
34XXWT-6	PROBP 3400, WALL, AU
34XXWT-B	PROBP 3400, WALL, NA

Appendix B: Relationship Between MDD and MDR Codes

Note: SureTemp Plus is not included in the table below as there is no substitute device

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
Braun ThermoScan PRO 6000 Ear Thermometer					
06000-200	PRO 6000 W/SMALL CRADLE	09000-200 (substitute)	"DISCO" Ear Thermometer	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
06000-300	PRO 6000 W/LARGE CRADLE	09000-200 (substitute)	"DISCO" Ear Thermometer	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
PROBP 3400 Digital Blood Pressure Device					

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34XF	PROBP 3400 SUREBP, UNIT ONLY	4000 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XF-EX	PROBP 3400 STANDARD W/SUREBP EXCHANGE	4000 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFHT-2	PROBP 3400, SUREBP, HANDHELD, EU	4000-2 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFHT-4	PROBP 3400, SUREBP, HANDHELD, UK	4000-4 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFHT-6	PROBP 3400, SUREBP, HANDHELD, AU	4000-6 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFHT-B	PROBP 3400, SUREBP, WALL	4000-B (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFST-2	PROBP 3400, SUREBP, MOBILE, EU	4000-2 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFST-4	PROBP 3400, SUREBP, MOBILE, UK	4000-4 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFST-6	PROBP 3400, SUREBP, MOBILE, AU	4000-6 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFST-B	PROBP 3400, SUREBP, MOBILE	4000-B (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFWT-2	PROBP 3400, SUREBP, WALL, EU	4000-2 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA

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34XFWT-4	PROBP 3400, SUREBP, WALL, UK	4000-4 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFWT-6	PROBP 3400, SUREBP, WALL, AU	4000-6 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XFWT-B	PROBP 3400, SUREBP, WALL	4000-B (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XX	PROBP 3400 STANDARD, UNIT ONLY	4000 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XX-EX	PROBP 3400 STANDARD EXCHANGE	4000 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXHT-2	PROBP 3400, HANDHELD, EU	4000-2 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXHT-4	PROBP 3400, HANDHELD, UK	4000-4 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXHT-6	PROBP 3400, HANDHELD, AU	4000-6 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXHT-B	PROBP 3400, HANDHELD, NA	4000-B (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXST-2	PROBP 3400, MOBILE, EU	4000-2 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXST-4	PROBP 3400, MOBILE, UK	4000-4 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXST-6	PROBP 3400, MOBILE, AU	4000-6 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA

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34XXST-B	PROBP 3400, MOBILE, NA	4000-B (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXWT-2	PROBP 3400, WALL, EU	4000-2 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXWT-4	PROBP 3400, WALL, UK	4000-4 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXWT-6	PROBP 3400, WALL, AU	4000-6 (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA
34XXWT-B	PROBP 3400, WALL, NA	4000-B (substitute)	ProBP 4000 Digital Blood Pressure Device	TuV	Welch Allyn, Inc. 4341 State Street Rd. Skaneateles Falls, NY 13153, USA

[2] Refers to procedure GQP-09-27 for a definition of substitute device