EU Declaration of Conformity (DoC)

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

80025603 Version G	Welch Allyn Braun IR Thermometer Accessories

Manufacturer Name and Address:

Welch Allyn, Inc.

4341 State Street Road

Skaneateles Falls, NY 13153

USA

Manufacturer Single Registration Number (SRN): US-MF-000013394

Authorised Representative Name and Address:

Welch Allyn Limited

Navan Business Park, Dublin Road

Navan, Co. Meath, C15 AW22

Ireland

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

+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++

Other relevant Directives, Regulations and Union Legislations that the device is in conformity with:

- *Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (CCV).*

Common Specifications Applied: N/A

Product/Trade Name and Product Code or REF. number: Refer to Product Code List

Intended Purpose/Use: Refer to Product Code List

Device Risk Class: Class I

Product Basic UDI-DI Number: Refer to Product Code List

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MDR EU Certificate(s) No.: N/A
Conformity Assessment Description/Annexes: Annex II and III
Notified Body Name and Address: DQS Medizinprodukte GmbH August-Schanze-Straße 21, 60433 Frankfurt am Main Notified Body Identification Number: 0297

+++ This Declaration is made on the following basis:
• For devices with a MDR EU Certificate issued by a Notified Body:
  ○ The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.
  ○ The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.
• For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature.
• Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
• Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Authorised Signatory:	
Name and Title:	Joseph Olsavsky
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA
Date of Issue:	14-Dec-2023
Signature:	**Signature:** JOSEPH OLSAVSKY *Electronically signed by: JOSEPH OLSAVSKY Reason: I approve this document Date: Dec 14, 2023 13:19 EST* **Email:** joseph_olsavsky@baxter.com

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Business: Welch Allyn, Inc.

MDR EU Certificate(s) Reference:	N/A
Conformity Assessment Description/Annexes:	Annex II and III
Device Risk Class:	Class I
Sterilization Method(s):	N/A
Sterilization Facility/Facilities:	N/A
Manufacturing Facility/Facilities:	PRO6000 Charging Stations: Key Tronic Juarez Plant 3 Tomas Becket 2220 Parque Industrial Gema Ciudad. Juarez, Chih. Mexico C.P. 32270 Pro6000 Rechargeable Battery: Key Tronic Juarez Plant 2 El Dorado #7851 Parque Industrial Gema Ciudad. Juarez, Chih. Mexico C.P. 32380

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Product Code or REF. number	Product or Trade Name	Intended Purpose/Use	Basic UDI-DI	STED ID Number	Date of initial MDR CE Marking *(This corresponds to the date when the EU Declaration of Conformity was signed for the first time)*
06000-125	PRO 6000 CHARGING STATION EU	The Braun® Thermoscan® PRO 6000 Ear Thermometer is indicated for use by clinicians for the intermittent measurement of human body temperature for patients having ages ranging from normal weight (full term) newborn to geriatric adults in a professional healthcare use environment. The probe cover is used as a sanitary barrier between the infrared thermometer and the ear canal.	0732094GMN901009EY	60097686	2 December 2019
06000-150	PRO 6000 CHARGING STATION AU		0732094GMN901009EY	60097686	2 December 2019
06000-100	PRO 6000 CHARGING STATION NA		0732094GMN901009EY	60097686	2 December 2019
104894	PRO 6000 RECHARGEABLE BATTERY		0732094GMN901122EV	60097686	2 December 2019

Signature: Katherine Love *Electronically signed by: Katherine Love Reason: I approve this document Date: Dec 14. 2023 12:52 EST*

Email: katherine_love@baxter.com

This Product Code List has been reviewed and verified by: _____ Date: 14 December 2023
(*Name/Surname/Signature*)

Title: *Global Regulatory Lead*