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).

80030804 Rev. A	Braun ThermoScan Pro6000 Probe Covers

Manufacturer Name and Address:

Welch Allyn, Inc.

4341 State Street Road

Skaneateles Falls, NY 13153, USA

Manufacturer Single Registration Number (SRN): US-MF-000013364

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: N/A

Common Specifications Applied: N/A

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

06000-005	BRAUN PRO 6000 PC 5K PKG (MN)
06000-800	BRAUN PRO 6000 PC 800 PKG (EU)
06000-801	BRAUN PRO 6000 PC 800 PKG (MN)

Intended Purpose/Use:

The Braun ThermoScan PRO 6000 Ear thermometer is indicated 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 use environment. The probe cover is used as a sanitary barrier between the infrared thermometer and the ear canal.

Device Risk Class: Class I

Product Basic UDI-DI Number: 0732094GMN901010AN3

MDR EU Certificate(s) No.: N/A

Conformity Assessment Description/Annexes: Annex II and III

Notified Body Name and Address: N/A

Notified Body Identification Number: N/A

+++ 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:

EU Declaration of Conformity (DoC)

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Name and Title:	Joseph Olsavsky
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA
Date of Issue:	14-May-2024
Signature:	**Signature:** JOSEPH OLSAVSKY *Electronically signed by: JOSEPH OLSAVSKY Reason: I approve this document Date: Mav 14. 2024 16:16 EDT* **Email:** joseph_olsavsky@baxter.com