DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and
- 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 as amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 (RoHS3).

Document Number 80025574	Version G	
Product Name	Braun Thermoscan Pro 6000 Ear Thermometer	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
EC Certificates Declaration of Conformity Validity	EC Certificate 314505 MR2 Expiry Date: 2024-05-26	
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road Navan Co. Meath C15 AW22 Ireland	SRN: IE-AR-000000768
REF #	06000-200 Pro 6000 w/Small Cradle 06000-300 Pro 6000 w/Large Cradle 105948 Srv Kit, Braun Pro 6000 Thermometer	
	901054 Ear Thermometer 901010 Accessory Thermometry	
Radio equipment	N/A	
Object of the declaration	 Braun Thermoscan Pro 6000 Ear Thermometer	
Medical Device Conformity Assessment Route Annex	Annex II	

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Medical Device Classification	IIa (Thermometer)
Medical Device Classification Rule	10
GMDN Code and Term	17887 Infrared patient thermometer, ear
UMDNS Code and Term	17887 Thermometers, Electronic, Infrared, Ear
Standards	Refer to Appendix A
	Accessories
REF #	06000-005 : Hillrom Pro 6000 PC 5K PKG (MN) 06000-800 : Hillrom Pro 6000 PC 800 PKG (EU) 06000-801 : Hillrom Pro 6000 PC 800 PKG (MN)
Object of the declaration	  Braun Thermoscan Pro 6000 Ear Thermometer Disposable Probe Covers
Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	IIa (Thermometer Probe Cover)
Medical Device Classification Rule	5
GMDN Code and Term	13116 Electronic Thermometer Probe Cover
UMDNS Code and Term	13116 Covers, Thermometer Probe
Standards	Refer to Appendix A

Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

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Authorised Signatory

Joshua Kim
Senior Manager
Global Regulatory Affairs

2022 · 01 · 04
Date

Skaneateles Falls NY, USA
Place of Issue

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN 60601-1	2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2	2015	Medical electrical equipment_- Part_1-2: General requirements for basic safety and essential performance_- Collateral standard: Electromagnetic compatibility_- Requirements and tests
	EN 60601-1-6	2013	Medical electrical equipment_- General requirements for basic safety and essential performance_- Collateral Standard: Usability
	EN ISO 10993-1	2009	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
	EN ISO 15223-1	2016	Medical devices_- Symbols to be used with medical device labels, labelling and information to be supplied_- Part_1: General requirements
	EN ISO 80601-2-56	2009	Medical electrical equipment_- Part_2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
	EN 62304	2006	Medical device software - Software life-cycle processes
	EN 62366-1	2015	Medical devices_- Application of usability engineering to medical devices
	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 20417	2021	Information supplied by the manufacturer of medical devices
Directive 2011/65/EU + (EU) 2015/863	EN IEC 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances