

Document Number: 80025574 **Version:** B

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

- > the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- > the 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 (RoHS)

Product Name: Welch Allyn Braun IR Thermometer

Manufacturer's Name and Welch Allyn, Inc.

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

Product Name: Welch Allyn Limited

Address: Navan Business Park, Dublin Road, Navan, Co Meath, C15 AW22, Ireland

Notified Body: DQS Medizinprodukte GmbH

August-Schanz-Str.21, 60433 Frankfurt am Main

Notified Body Number: 0297

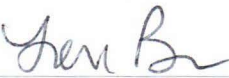
Conformity Assessment Route: Annex II

Part Numbers: Refer to Appendix A for Part Numbers and their corresponding Class, Class Rule, GMDN Code, and UMDNS Code.

Standards: Refer to Appendix B

Validity Limitation: Initial release

Note: The Notified Body indicated above was only responsible to review compliance of the medical device to the Medical Devices Directive (MDD), not the Restriction of Hazardous Substances (RoHS) Directive.


Lori Burns
Regulatory Affairs Dir QA/RA

2020-09-08

Date

Skaneateles Falls, NY, USA

Place of Issue

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Appendix A: Part Numbers

1. Device:

Class:	IIa	
Class Rule:	10	
GMDN Code and Term:	17887	Infrared patient thermometer, ear
UMDNS Code and Term	17887	Thermometers, Electronic, Infrared, Ear
REF	#	Description
901054	06000-200	PRO 6000 W/SMALL CRADLE
901054	06000-300	PRO 6000 W/LARGE CRADLE

2. Accessories:

Class:	IIa	
Class Rule:	5	
GMDN Code and Term:	13116	Electronic thermometer probe cover
UMDNS Code and Term	17887	Thermometers, Electronic, Infrared, Ear
REF	#	Description
901010	06000-005	Hillrom PRO 6000 PC 5K PKG (MN)
901010	06000-800	Hillrom PRO 6000 PC 800 PKG (EU)
901010	06000-801	Hillrom PRO 6000 PC 800 PKG (MN)

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Appendix B: Standards (and Common Specifications)

Number	Title
EN 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
EN 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
EN 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
EN 62304	Medical Device Software - Software Life-Cycle Processes
EN ISO 80601-2-56	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN/ISO 15223-1	Medical Devices - Symbols to be Used with medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements
EN ISO 14155	Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice
MEDDEV 2.7/1	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
ISO 7000	Graphical Symbols for Use On Equipment - Registered Symbols
IEC 60417	Graphical Symbols for Use on Equipment (online database)