

**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

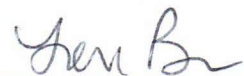
**Conformity Assessment Route:** Annex II

**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.



2020-09-08

Skaneateles Falls, NY, USA

Lori Burns  
Regulatory Affairs Dir QA/RA

Date

Place of Issue

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### Appendix A: Part Numbers

#### 1. Device:

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

#### 2. Accessories:

<b>Class:</b>	IIa	
<b>Class Rule:</b>	5	
<b>GMDN Code and Term:</b>	13116	Electronic thermometer probe cover
<b>UMDNS Code and Term</b>	17887	Thermometers, Electronic, Infrared, Ear
<b>REF</b>	<b>#</b>	<b>Description</b>
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)