WelchAllyn[®]

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Document Number: 80025574 Version: A

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 Address:	Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153 USA			
EC REP	Welch Allyn Limited 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.

Yua B

2014/12/2

Skaneateles Falls, NY, USA

Lori Burns

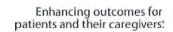
Date

Place of Issue

Regulatory Affairs Dir QA/RA

Page 1 of 3

Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153 USA www.welchallyn.com





DECLARATION OF CONFORMITY



(in accordance with ISO/IEC 17050-1)

Document Number: 80025574

Version: A

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:	Па				
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		BRAUN PRO 6000 PC 5K PKG (MN)		
901010	06000-800		BRAUN PRO 6000 PC 800 PKG (EU)		
901010	06000-801		BRAUN PRO 6000 PC 800 PKG (MN)		

DECLARATION OF CONFORMITY



(in accordance with ISO/IEC 17050-1)

Document Number: 80025574

Version: A

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 Labesl, 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)			

