MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian ***Therapeutic Goods (Medical Devices) Regulations 2002*** relating to the devices stated in the attached Schedule

We, **Kaz USA, Inc**, 250 Turnpike Road, Southborough, MA, USA declare under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the EC Directive(s):

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Reference: *Kaz-PRO6000-01*

Medical Device(s): *See Attached Schedule Kaz-PRO6000-01*

Classification: *See Attached Schedule Kaz-PRO6000-01*

GMDN Code and Term: *See Attached Schedule for the GMDN code and term*

Scope of Application: *All*

For each kind of medical device to which the Declaration of Conformity (not requiring assessment by Secretary) procedures have been applied the product quality assurance procedures have also been applied.

Product Quality Management System Certificate:

Notified body: DQS GmbH, D-60433, Frankfurt, Germany (registration number: 0297)

DQS issued Conformity Assessment Certificates:

Production Quality Management System ISO 13485:2003

European Medical Devices Directive Annex V Certificate;

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Standards Applied:

Reference Number	Title	Date of issue
EN IEC 60601-1	Medical electrical equipment - Part 1: General requirements for Basic Safety and Essential Performance	2006
EN IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2007
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing	2009
EN 12470-5	Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)	2003
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
IEC 62304	Medical Device Software – Software Lifecycle Processes	2006
EN 1041	Information Supplied by the manufacturer with Medical Devices	2008
EN980	Symbols for Use in the Labeling of Medical Devices	2008

Raj S. Kasbekar		Southborough, MA	August 24, 2015
Global VP, Regulatory Affairs	Legally binding signature	Place	Date

Company Stamp:

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Schedule Reference: **Kaz-PRO6000-01**

ThermoScan® Braun Thermometer				
Medical Devices		**Classification**	**GMDN**	**Conformity assessment per EU MDD 93/42/CE**
Kaz Reference	Welch Allyn			
ThermoScan PRO 6000	**Thermometer** Part Number: 06000-550 Part Number: 06000-150 Part Number: 06000-200 Part Number: 06000-300 **Accessories**: Part Number: 104894 –Rechargeable Battery Pack Part Number: 106191 – PRO6000 Small Cradle Part Number: 106192 – PRO6000 Large Cradle Part Number: 106201 – 6 ft tether for PRO 6000 Part Number: 106204 –Tether for PRO 6000 with 9 ft cord Part Number: 105786 – Pro 6000 USB Adapter Part Number: 105789 – Pro 6000 Probe Cover Box Holder Part Number: 106205 – Battery Door PRO 6000 Part Number: 106378 – Replacement CD DFU for Charge Station (without TC)	IIa(Annex IX rule 5) Rule 4.3 – Australia	17887	Annex V (Directive 93/42/CE)