

EC Declaration of Conformity

We, **Kaz USA, Inc.**, a Helen of Troy Company, located at 400 Donald Lynch Boulevard, Marlborough, MA 01752 (country of legal manufacture: 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

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

Name

Type or model

Thermoscan®
Pro 6000 (GMDN: 17887)

06000-425, 06000-525,
06000-125, 06000-200,
06000-300, 06000-400,
410422, 411543

Standards Applied:

Reference Number	Title	Date of Issue
EN 12470-5	Clinical Thermometers- Part 5 Performance of Infra-Red Thermometers	2003
	Part 5: Annex A Clinical Performance Testing	2003
EN IEC 60601-1	Medical Electric 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 ISO 14971	Medical devices- Application of risk management to medical devices.	2012
EN 980	Symbols for Use in the Labeling of Medical Devices	2008
EN 1041	Information supplied by the manufacturer with Medical Devices	2008
IEC 62304	Medical Device Software-Software Life Cycle Processes	2006

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Conformity assessment procedure:

Device Classification	Annex	GMDN
IIa (Annex IX rule 10)	II	17887

The Technical Documentation is the responsibility of: Kaz USA, Inc., a Helen of Troy Company, 400 Donald Lynch Boulevard, Marlborough, MA 01752.

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Raj S. Kasbekar



Marlborough, MA, USA

9/24/2018

Global VP, Regulatory
Affairs

Legally binding signature

Place

Date

Company Stamp:

