

# 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/Model

Probe Covers & Lens Filters: See below

<b>Medical Devices</b>	<b>GMDN</b>	<b>Conformity Assessment (93/42/CE)</b>
PC 20	13116	Annex II
PC200	13116	Annex II
PC800	13116	Annex II
PC5000	13116	Annex II
LF 20	13116	Annex II
LF 40	13116	Annex II
04000-800	13116	Annex II
05075-800	13116	Annex II
05075-005	13116	Annex II
05075-200	13116	Annex II
05075-001	13116	Annex II
06000-005	13116	Annex II
06000-800	13116	Annex II
06000-801	13116	Annex II

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## Standards Applied

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	2007
EN 980	Symbols for Use in the Labeling of Medical Devices	2008

## Conformity assessment procedure:

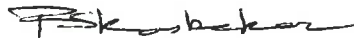
Device Classification	Annex	GMDN
IIa (Annex IX rule 5)	II	13116

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 9/24/2018

Global VP, Regulatory Affairs      Legally binding signature

Place

Date

Company Stamp:

