EC Declaration of Conformity

We, **Kaz USA**, 250 Turnpike Road, Southborough, MA 01772 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

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

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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)	V	13116

The Technical Documentation is the responsibility of: Kaz USA, 250 Turnpike Road, Southborough, MA 01772.

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Raj S. Kasbekar  Southborough, MA 2/18/2015

Global VP, Regulatory Affairs | Legally binding signature | Place | Date

Company Stamp: