EC Declaration of Conformity

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

EC Declaration of Conformity

Conformity assessment procedure:

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

The Technical Documentation is the responsibility of: Kaz USA, 400 Donald Lynch Boulevard, Marlborough, MA 01752

Authorized Representative: Kaz Europe Sarl, Place Chauderon 18, 1003 Lausanne, Switzerland

Notified body: DQS Medizinprodukte GmbH, August Schanz Str.21, D-60433, Frankfurt, Germany (registration number: 0297)

Raj S. Kasbekar [signature] Massachusetts, 09/25/2016

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

Company Stamp:

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Name
Type/Model
Probe Covers & Lens Filters: See below

Medical Devices	GMDN	Conformity Assessment (93/42/CE)
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

EC Declaration of Conformity

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

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Raj S. Kasbekar — Marlborough, MA 9/25/2016

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