Kindara, Inc. Declaration of Conformity

In accordance with Council Directive 93/42/EEC concerning medical devices

1) **Product: Wink Electronic Thermometer**

2) **Manufacturer Address**
3004 Arapahoe Avenue
Boulder, CO 80301 USA

European Representative

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

3) Object of the declaration: Wink, a Class I medical device (with measuring function) according to Rule 12**, Annex IX, of the Medial Device Directive 93/42/EEC.**

4) **The object of the declaration described above is in conformity with:**

Document No.	***Title***	***Edition/Date of issue***
EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	2012

and has additionally been, and is, designed, tested, and produced with reference to the following list (section 5) of broadly applicable standards and normative documents.

5) Document No.	***Title***	***Edition/Date of issue***
EN ISO 14971	Medical Devices – Application of Risk Management to Medical Devices	2012
EN 1041	Information supplied by the manufacturer of medical devices	2008
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	2009
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2012
EN ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements (ISO 15223-1:2012)	2012
EN ISO 19011	Guidelines for auditing management systems (ISO 19011:2011)	2011

6) Additional information:

Kindara, Inc. further certifies that the Wink electronic thermometer conforms with the Essential Requirements, as listed in Annex I to Council Directive 93/42/EEC concerning medical devices, the Medical Device Directive (MDD), as amended under Directive 2007/47/EC. Kindara, Inc. has established a Full Quality System route for assessment in accord with Annex II of the MDD.

Kindara has verified the mutual compatibility of Wink and its companion digital application in accordance with the manufacturers' instructions and has carried out operations in accordance with these instructions; has packaged Wink and supplied relevant information incorporating relevant instructions; and this whole activity is subjected to appropriate methods of internal control and inspection, in accordance with Article 12 of the Medical Device Directive (MDD), as amended under Directive 2007/47/EC.

Kindara, Inc. maintains the following Certificates issued by BSI, a Notified Body according to the Council Directive 93/42/EEC concerning medical devices with identification no. 0086, Certificate of Registration No. MD 642563, and CE Mark Certificate No. CE 642031. This Declaration of Conformity applies to the lots/batches of Wink branded by Kindara, Inc. (Boulder, Colorado, USA) as 0001 through 0015, produced between 2 May 2016 and 5 May 2017.

Signed for and on behalf of Kindara, Inc. Boulder, Colorado, USA:

_____ Date 05/24/2016 _____ Date 05/24/2016

_____ Date 05/24/2016 _____ Date 05/24/2016

7) Issued at Boulder, Colorado on 23 May 2016