File name: Declaration of Conformity

File No.: XW-ET Series B-CE-16

Device name: Digital Clinical Thermometer

Models: FDTH-V0-1, FDTH-V0-2, FDTH-V0-8, FDTH-V0-9, and FDTH-V0-12

Signature  **May 2, 2013**

Reanny Wang **Date**

Title: Management Representative

Manufacturer: Famidoc Technology Co., Ltd.

Address: No.212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town, Dongguan 523853, Guangdong Province, P.R. China.

European Representative: Shanghai International Holding Corp.GmbH

Address: Eiffestrasse 80, 20537 Hamburg Germany

Product: Digital Clinical Thermometer

Models: FDTH-V0-1, FDTH-V0-2, FDTH-V0-8, FDTH-V0-9 and FDTH-V0-12

Classification: II a (MDD Annex IX, Rule 10) **UMDNS: 14032**

GMDNS：14032

Conformity assessment route: Annex II (Section 4) of the Directive 93/42/EEC on Medical Devices.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards and laws of Sweden. All supporting documentations are retained under the premises of the manufacturer and notify body.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 2007.

Standard list:

EN ISO 13485:2012/AC:2012
EN ISO 15223-1:2012
EN 1041:2008
EN ISO 780:1999
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 14971:2012

EN 60601-1:2006 /AC:2010
EN 60601-1-2:2007/AC:2010
EN 60601-1-6:2010
EN 12470-3:2000+A1:2009
EN 62304:2006/AC:2008

Notified Body: SGS United Kingdom Ltd,
202B Worle Parkway, Waeston-super-Mare, BS22 6WA UK
(EC) Certificate: CN11/30547
Identification number of notified body: 0120
Expiration date of the Certificate: 2016-5-19