



File number: XW-ETB-CE Series 16

Version: V2.0

The date: 2.May 2013

File name: Declaration of conformity

File number: 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

A red circular stamp is placed over a handwritten signature. The stamp contains a five-pointed star in the center and Chinese characters around the perimeter. The signature is written in black ink and appears to be 'Reany Wang'. Below the signature, the name 'Reany Wang' is printed in a bold, black, sans-serif font.

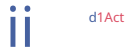
Reany Wang

Name: Executive Deputy

May 2

2013

The date



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Date: 2013.

May 2

Manufacturer: Famidoc Technology Co., Ltd.

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

European representative: Shanghai International Holding Corp. GmbH

Address: Eiffelstrasse 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: IIa (Annex IX, MOD. rule)

UMDNS: 14032

GMDNS: 14032

Conformity assessment method: Annex II to Directive 93/42 / EEC concerning medical devices. Annex I (section 4).

Tools.

We hereby declare that mentioned above the products comply with the following EU Council directives and standards and provisions of Swedish law. All of them supporting documents kept at the premises of the manufacturer and the notified body.

GUIDELINES

General valid instructions:

Medical Devices Directive: COUNCIL DIRECTIVE 93/42 / EEC of 1993 on
medical devices (Directive 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 ISO

15223-1: 2012 EN ISO 15223-

1: 2012

EN 1041: 2008

ENISO 780: 1999

ENISO 10993-1: 2009 / AC: 2010

ENISO 10993-5: 2009

ENISO 10993-10: 2010

ENISO 14971: 2012

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IN 60601-1: 2006

/ AC: 2010EN60601-1-

2: 2007 / AC: 2010EN60601-

1-6: 2010

EN12470-3: 2000 + A1: 2009

EN62304: 2006 / AC: 2008

Notified body: SGSUnited Kingdom Ltd,

202B Werle Parkway, Waeston-super-Mare, BS22 6WA UK

Certificate(EC): CN11 / 30547

IdentificationNotifying authority number:0120

Certificate expiration date: 2016-5-19