2020

FDA REGISTRATION CERTIFICATE

Certificate No.: JF-FDA-1105-0013

Certificate Holder: COMPER CHUANGXIANG (BEIJING) TECHNOLOGY CO., LTD.

Building 1, Unit 4, Room 102, 103 1st Floor, No.1 Kangding Street, Beijing Economic Technological Development Area, 100176, Beijing, China

Registration Number: 3013517659

Owner/Operator Number: 10053396

Data of verification: January 05th , 2020

Listing Number	Product Codes	Device Name
D361114	FLL (K191668)	Thermometer, electronic, clinical
D281797	LHD	Device, Fertility diagnostic, proceptive

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.

2424 Morris Ave 818 Union

NEW JERSEY 07083

United States

Signature:

Fanny Zhao G.M

FDA

SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.

Test Verification of Conformity

Certificate No.: CTC14050011201 RID: 85118

Issued Date: Oct 27, 2015

The sample, as described herewith, was tested pursuant to the testing standard :

IEC 62321-3000, IEC 62321-3013

and all the test results comply with the requirements of :

RoHS Directive 2011/65/EU

Restriction of the use of certain Hazardous Substance in electrical and electronic equipment

Applicant: Comper Chuangxiang(Beijing) Technology Co., Ltd

Room 103-103 1st Floor, Building 4, No.1 Kangding Street, Daxing District, Beijing

Manufacturer: Comper Chuangxiang(Beijing) Technology Co., Ltd

Room 103-103 1st Floor, Building 4, No.1 Kangding Street, Daxing District, Beijing

Sample Name: Comper Smart Fertility Tracker

Brand: Comper

Sample Model(s): SBITK

Laboratory: Shenzhen Huatongwei International Inspection Co., Ltd.

4/F East, Huping Building, Huping Road, Luohu, Shenzhen, China

Tel: 86-755-25714018 Fax: 86-755-25716080

Http://www.szhtin.com.cn E-mail: cs@szhtin.com.cn

RoHS

Note: The certification is only valid for the submitted sample(s), in conjunction with the test data detailed in test report.

For and on behalf of
Shenzhen Huatongwei International Inspection Co., Ltd.

Authorized by:

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 18 02 99273 004

Holder of Certificate: Comper Chuangxiang(Beijing) Technology. Co., Ltd.

Building 1,Unit 4,Room 102,103
1st Floor, No.1 Kangding Street
Beijing Economic Technological Development Area
100176 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Comper Chuangxiang(Beijing) Technology. Co., Ltd.
Building 1,Unit 4,Room 102,103, 1st Floor, No.1 Kangding Street, Beijing Economic Technological Development Area, 100176 Beijing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design, Development, Production and Distribution of Smart Doppler Fetal Monitor.

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2006)
DIN EN ISO 13485:2012
Upgrade required until 2019-02-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SJ1867901

Valid from: 2018-02-12
Valid until: 2021-02-11

Date, 2018-02-12

Stefan Prell

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DAkkS

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV