

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial
Park, Songbai Road, Xili Street, Nanshan District,
518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Spot-Check Monitor, and accessories listed below

Model: PC-102, PC-203, PC-303

CLASSIFICATION - ANNEX IX: Class IIa, Rule 10

CONFORMITY ASSESSMENT ROUTE: Annex II excluding(4)

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 (AMENDED BY DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

LIST OF ACCESSORY OF PC-303/PC-203:
THERMOMETER PC00050004

WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

ISO 13485:2016	EN/ISO 14971: 2012	EN 60601-1: 2006+A1: 2013
EN 60601-1-2: 2007+AC2010	IEC60601-1-6:2010+A1: 2013	EN 80601-2-30: 2011
ISO 80601-2-61: 2011	EN/ISO 80601-2-56: 2009	IEC 60601-1-11: 2015
ISO 10993-1: 2018	ISO 10993-5: 2009	ISO 10993-10: 2010
EN ISO 14155: 2011/AC:2011	EN 1041: 2008+A1:2013	ISO 15233-1: 2016
		2011/65/EU

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1 049076 0016 Rev .02

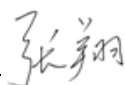
EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

START OF CE-MARKING: OCT.15, 2010

PLACE, DATE OF DECLARATION: Floor 5, BLD 9, Baiwangxin High-Tech Industrial
Park, Songbai Road, Xili Street, Nanshan District,
518110 Shenzhen, PEOPLE'S REPUBLIC OF
CHINA,

SIGNATURE:



NAME:	FEB 05, 2020
POSITION:	Management Representative

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