

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

MANUFACTURER: Shenzhen Creative Industry Co., Ltd.
2/F, Block 3, Nanyou Tian'an Industry Town, 518054
Shenzhen, GD, P. R. China

MEDICAL DEVICE: Fetal Doppler
MODEL: PC-860B/Prince-200B
PC-860A/Prince-200A

CLASSIFICATION - ANNEX IX: Class IIa, Rule 10

CONFORMITY ASSESSMENT ROUTE: Annex II .3

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 (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

LIST OF ACCESSORIES:

FETAL DOPPLER PROBE (15070001) AND FETAL MONITOR PROBE (15070003)

STANDARDS APPLIED:

EN/ISO 13485: 2012+AC: 2012	EN/ISO 14971: 2012	EN 60601-1: 2006+A1: 2013
IEC 60601-1-2: 2014	EN 60601-1-6: 2010	IEC 60601-2-37: 2007
EN ISO 10993-1: 2009	EN ISO 10993-5: 2009	EN ISO 10993-10: 2010
EN 14155: 2011	ISO 15233-1: 2012	EN 1041: 2008
2011/65/EU		

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

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1170749076014

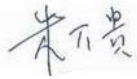


EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING: Oct. 15, 2010

PLACE, DATE OF DECLARATION: 2/F, Block 3, Nanyou Tian'an Industry Town, 518054
Shenzhen, GD, P.R. China, Jan.15, 2018

SIGNATURE:

NAME:  Jan. 15, 2018
POSITION: Management Representative