

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: Patient Monitor (Vital Signs Monitor)
MODEL: PC-900/PC-900S/PC-900SNT/PC-900SNET
Classic-90/PC-900pro/PC-900pro SNET/PC-900plus

CLASSIFICATION - ANNEX IX: Class IIb, 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 CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

ISO 13485: 2003	ISO 14971: 2007	EN 60601-1: 2006/AC: 2010
EN 60601-1-2: 2007	EN 60601-1-6: 2010	EN 60601-1-8: 2007
EN 60601-2-49: 2011	IEC 60601-2-27: 2011	EN 60601-2-30: 2009
ISO 80601-2-61: 2011	ISO 80601-2-56: 2009	ISO 10993-1: 2009
ISO 10993-5: 2009	ISO 10993-10: 2010	EN 14155: 2011
EN 1041: 2008	ISO 15233-1: 2012	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