

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: Capnograph and Oximeter and accessories (listed below)
Model: PC-900B, Capno Cube

CLASSIFICATION - ANNEX IX: Class IIb, 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 ACCESSORIES FOR PC-900B:
SAMPLING LINE (15100110), NASAL TUBE (15100004), FILTER (2500-0000218), AIRWAY ADAPTER (15100210), SPO2 PROBE, AC/DC ADAPTER, USB CABLE AND SO ON.

LIST OF ACCESSORIES FOR CAPNO CUBE:
ADULT ADAPTER (2301-0000017), PEDIATRIC/NEONATE ADAPTER (2301-0000029) AND SO ON.

WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

ISO 10993-1:2009	ISO 10993-5:2009	ISO 10993-10:2010	
EN 1041:2008+A1:2013E	IEC 60601-1-8:2006+A1:2012	IEC 60601-1:2005+A1:2012(E)	
IEC 62304:2006 +A1:2015	IEC 60601-1-2:2014	EN ISO 15223-1:2012	
EN 60601-1-6 :2015	ISO 80601-2-55:2018	EN ISO 14971:2012	
IEC 60601-2-49:2011 (NOT APPLICABLE FOR CAPNO CUBE)	ISO 80601-2-61:2017 (NOT APPLICABLE FOR CAPNO CUBE)	ISO 13485:2016	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