

## 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, Shenzhen,P.R.China

**MEDICAL DEVICE:** Multi Parameter Monitors for Capnography and Pulse Oximetry  
**MODEL:** PC-900B/Capno Cube

**GMDN CODE:** 36872

**CLASSIFICATION - ANNEX IX:** Class IIb, Rule 10

**CONFORMITY ASSESSMENT ROUNT:** 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. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

### STANDARDS APPLIED:

EN ISO 13485:2016	EN ISO 14971:2012	IEC 60601-1:2005+A1:2012
IEC 60601-1-2:2014	IEC 60601-1-6:2010+A1:2013	IEC 60601-1-8:2006+A1:2012
IEC 80601-2-49:2018	ISO 80601-2-55:2018	ISO 80601-2-61:2017
IEC 62304:2006+A1:2015	ISO 10993-1:2018	ISO 10993-5:2009
ISO 10993-10:2010	EN ISO 15223-1:2021	EN1041:2008+A1:2013

**NOTIFIED BODY:** TÜV SÜD Product service GmbH  
Ridlerstr 65, D-80339 München, Germany

**IDENTIFICATION NUMBER:** 0123

**(EC)CERTIFICATE(S):** G1 049076 0016 Rev .03

**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestra ß e 80, 20537 Hamburg, Germany

### START OF CE-MARKING:

**PLACE, DATE OF DECLARATION:** Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District,Shenzhen,P.R.China

### SIGNATURE:

Name:



May 10, 2022

Position: Management Representative