DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/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: Sample line(15100110), Filter(2500-0000218), Airway Adapter(15100210),

CLASSIFICATION - ANNEX IX: Class IIa, Rule2

CONFORMITY ASSESSMENT ROUNT: Annex II excluding(4)

Note: The above accessories are only applicable to the device Multi Parameter Monitors for Capnography and Pulse Oximetry produced by shenzhen Creative Industry Co., Ltd. Which has been CE certified.

WE,**shenzhen Creative Industry Co., Ltd**HEREWITH DECLARE THAT THE STATED MEDICAL DEVICESMEET 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	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 β 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: 张翔 May 13,2022

Position: Management Representative