DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/EC)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:	Patient Monitor
MODEL:	K10, K12, K15
CLASSIFICATION - ANNEX IX:	Class IIb, Rule 10
GMDN CODE:	33586
CONFORMITY ASSESSMENTROUTE:	Annex II excluding(4)

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/EC) 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	ENISO 14971: 2019	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 60601-2-49: 2018	IEC 60601-2-27: 2011	IEC80601-2-30: 2018
ISO 80601-2-61: 2017	ISO 80601-2-56: 2017+A1:2018	ISO 80601-2-55: 2018
IEC 62304: 2006+A1: 2015	EN 1041: 2008+A1: 2013	ENISO 15223-1: 2016
EN ISO 10993-1: 2020	EN ISO 10993-5: 2009	EN ISO 10993-10: 2013

NOTIFIED BODY:	TÜV SÜD Product Service GmbH . Ridlerstraβe 65.80339 Munich.Germany
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 049076 0016 Rev .03

EC REP

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

START OF CE-MARKING: OCT.15, 2010

PLACE, DATE OF DECLARATION: Shenzhen,Apr.8,2021

SIGNATURE:

NAME: Apr.8,2021

POSITION: Management Representative