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:	Patient Monitor
MODEL:	K10, K12, K15
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 (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:

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	EN 60601-1-8: 2007+A1: 2013
IEC 60601-2-49: 2011	IEC 60601-2-27: 2011	IEC 80601-2-30: 2009+A1: 2013
EN/ ISO 80601-2-61: 2017	EN/ISO 80601-2-56: 2017	ISO 80601-2-55: 2011
IEC 62304: 2006+A1: 2015	ISO 10993-1: 2009	ISO 10993-5: 2009
ISO 10993-10: 2010	EN/ISO 15233-1: 2012	EN 1041: 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 .02
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:	Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, Apr. 20, 2019
SIGNATURE:	**NAME:** Apr. 20, 2019 **POSITION:** Management Representative

Digitally signed by Botnaru Andrei
Date: 2024.08.13 16:37:56 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ