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:	Spot-Check Monitor
MODEL:	PC-303
CLASSIFICATION - ANNEX IX:	Class IIa, Rule 10
GMDN CODE:	57960
CONFORMITY ASSESSMENT ROUTE:	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	EN ISO 14971: 2012	IEC 60601-1: 2005+A1: 2012
IEC 60601-1-2: 2014	IEC 60601-1-6: 2010+A1:2013	IEC 80601-2-30: 2018
ISO 80601-2-61: 2017	ISO 80601-2-56: 2017+Amd.1:2018	IEC 62304: 2006+A1: 2015
EN ISO 10993-1: 2009/AC:2010	EN ISO 10993-5: 2009	EN ISO 10993-10: 2013
EN 1041: 2008+A1: 2013	EN ISO 15223-1: 2016	

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: 2014-12-09

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

Digitally signed by Cobzari-Turcan Rodica
Date: 2023.10.31 12:06:54 EET
Reason: MoldSign Signature
Location: Moldova

SIGNATURE:

NAME: Aug.26,2021

POSITION: Management Representative