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:	AIView V10, AIView V12
CLASSIFICATION - ANNEX IX:	Class IIb, Rule 10
GMDN CODE:	33586
CONFORMITY ASSESSMENT ROUTE:	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	EN 60601-1: 2006+A1: 2013
EN 60601-1-2: 2015	EN 60601-1-8: 2007+A1: 2013	EN IEC 80601-2-49:2019
EN 60601-2-27: 2014	EN 60601-2-25:2015	EN IEC 80601-2-30: 2019
EN ISO 80601-2-61: 2019	EN ISO 80601-2-56: 2017	EN ISO 80601-2-55: 2018
EN 60601-2-34:2014	EN 60601-1-6: 2010+A1:2015	EN 62366:2008+A1:2015
EN 62304: 2006+A1: 2015	EN 1041: 2008+A1: 2013	EN ISO 15223-1: 2016
EN ISO 10993-1: 2009/AC:2010	EN ISO 10993-5: 2009	EN ISO 10993-10: 2013

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, 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:

PLACE, DATE OF DECLARATION:	Shenzhen, Sept.30, 2021
SIGNATURE:	Sept.30, 2021
	NAME: Zhang Xiang **POSITION:** Management Representative