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: AIView VX， LeMonitor VX，MT10，AT10， AIView VS（Vital Signs Monitor）， LeMonitor VS（Vital Signs Monitor），MS10（Vital Signs Monitor），VS10（Vital Signs Monitor）

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:

ISO 13485: 2016	EN ISO 14971: 2019	IEC 60601-1: 2005+A1: 2012+A2:2020
IEC 60601-1-2: 2014+A1:2020	IEC 60601-1-6: 2010+A1:2013+A2:2020	IEC 60601-1-8: 2006+A1: 2012+A2:2020
IEC 60601-2-49: 2018	IEC 60601-2-27: 2011	IEC 80601-2-30: 2018
ISO 80601-2-61: 2017	ISO 80601-2-55: 2018	ISO 80601-2-56: 2017
IEC 62304: 2006+A1: 2015	EN ISO 15223-1: 2021	EN ISO 20417:2021
EN ISO 10993-1: 2020	EN ISO 10993-5: 2009	EN ISO 10993-10: 2021

NOTIFIED BODY: TÜV SÜD Product Service GmbH.
Ridlerstraβe 65.80339 Munich.Germany

IDENTIFICATION NUMBER: 0123

(EC) CERTIFICATE(S): G1 049076 0016 Rev .03

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

Valid Until: 2028-12-31

PLACE, DATE OF DECLARATION: Shenzhen, Jun. 28,2024

SIGNATURE: Zhang Xiang

NAME: Jun. 28,2024

POSITION: Management Representative