

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING
DIRECTIVE 2007/47/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 ASSESSMENT ROUTE:** Annex II excluding (4)

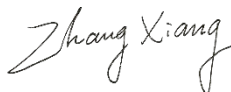
WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL
DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE
93/42/EEC OF 14 JUNE 1993 (AMENDED BY DIRECTIVE 2007/47/EC) CONCERNING MEDICAL
DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED 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.

Ridlerstraße 65.80339 Munich.Germany

IDENTIFICATION NUMBER: 0123**(EC) CERTIFICATE(S):** G1 049076 0016 Rev .03**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany**Valid Until:** 2028-12-31**PLACE, DATE OF DECLARATION:** Shenzhen, Jun. 28,2024**SIGNATURE:****NAME:** Jun. 28,2024**POSITION:** Management Representative