

## DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 CONCERNING MEDICAL DEVICES

**MANUFACTURER:** Edan Instruments, Inc.  
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China

**SRN:** CN-MF-000009957

**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH  
Eiffestrasse 80 20537 Hamburg Germany

**PRODUCT/MODEL:** Patient Monitor / iX10, iX12, iX15

**EMDN [NAME/CODE]:** VITAL SIGNS MONITORING INSTRUMENTS/ Z120302

**Basic UDI-DI:** 69444138iXS9L

**CLASSIFICATION:** Class IIb, Rule 10 According To Annex VIII of the MDR

**CONFORMITY ASSESSMENT ROUTE:** ANNEX IX EXCLUDING CHAPTER II.

WE, EDAN INSTRUMENTS, INC., HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICE.  
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.  
EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER

**STANDARDS APPLIED:** EN 60601-1: 2006+A1: 2013, EN 60601-1-2: 2015, EN 60601-1-6: 2010+A1: 2015, EN 60601-1-8: 2007+A1: 2013, EN 60601-2-25:2015, EN 60601-2-27: 2014, EN IEC 80601-2-30: 2019, EN 60601-2-34:2014, EN IEC 80601-2-49: 2019, EN ISO 80601-2-61: 2019, EN ISO 80601-2-55: 2018, EN ISO 80601-2-56: 2017+A1: 2020, EN ISO 81060-2: 2014, EN ISO 10993-1: 2020, EN ISO 10993-5: 2009, EN ISO 10993-10: 2013, EN ISO 14155: 2011, EN ISO 14971: 2019, EN 62304: 2006+A1: 2015, EN 62366-1: 2015, EN ISO 15223-1: 2021, EN 1041: 2008+A1: 2013, EN ISO 780: 2015

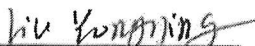
**NOTIFIED BODY:** TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

**IDENTIFICATION NUMBER** 0123

**(EC) CERTIFICATE(S):** G10 091264 0025 Rev. 01      VALID UNTIL: 2026-02-17

**START OF CE-MARKING:** 2022-10-31

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**SIGNATURE:**   
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE

