

## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

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

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

**PRODUCT/MODEL:** **Vital Signs Monitor / iM3s, iHM3s, iM3As, iM3Bs**  
*The accessories are used together with the product*

**GMDN [NAME/CODE]:** Single-patient physiologic monitoring system /33586

**CLASSIFICATION:** Class II b, Rule 10 According To Annex IX of the MDD

**CONFORMITY ASSESSMENT ROUTE:** Annex II excluding (4)

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 INCLUDING AMENDMENTS BY DIRECTIVE 2007/47/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

**STANDARDS APPLIED:** EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1: 2015, EN 62304: 2006+A1:2015, EN 62366-1: 2015, EN 80601-2-30:2010+A1:2015, EN ISO 81060-2:2014, EN ISO 80601-2-61:2019, ISO 80601-2-56:2017+A1:2018, EN IEC 80601-2-49:2019, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+ A1:2013, EN ISO 780:2015

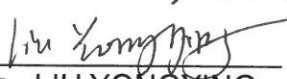
**NOTIFIED BODY:** TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

**IDENTIFICATION NUMBER** 0123

**(EC) CERTIFICATE(S):** G1 091264 0006 REV. 02    VALID UNTIL: 2022-09-17

**START OF CE-MARKING:** 2021-2-24

**PLACE, DATE OF ISSUE:** SHENZHEN, 2021.3.17

**SIGNATURE:**   
NAME **LIU YONGYING**  
**MANAGEMENT REPRESENTATIVE**