

## 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 (Europe)  
Eiffestrasse 80 D-20537 Hamburg Germany

**PRODUCT/MODEL:** **Vital Signs Monitor / M3, M3A**  
*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 DERECTIVE 2007/47/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

**STANDARDS APPLIED:** EN 60601-1:2006/A1:2013, EN 60601-1-2:2007/AC:2010, EN 60601-1-8: 2007, EN 62366: 2008, EN 62304:2006, EN 80601-2-30:2010, EN 60601-2-49:2015, EN ISO 80601-2-61:2011, EN ISO 80601-2-56:2012, EN ISO 81060-2: 2014, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO14971:2012, EN 980: 2008, EN 1041: 2008

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

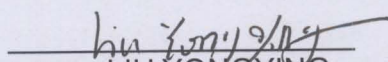
**IDENTIFICATION NUMBER** 

**(EC) CERTIFICATE(S):** G1 17 05 91264 006 VALID UNTIL: 2022-09-17

**START OF CE-MARKING:** 2008-5-26

**PLACE, DATE OF ISSUE:** SHENZHEN, 2017.8.12

**SIGNATURE:**

  
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE





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EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80 D-20537 Hamburg Germany

PRODUCT/MODEL: **Vital Signs Monitor / M3B**  
*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  
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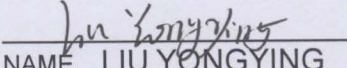
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