

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, IEC 80601-2-30:2009, ISO 81060-2:2013, ISO 80601-2-61:2011, ISO 80601-2-56:2009, IEC 60601-2-49: 2011, 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  0123

(EC) CERTIFICATE(S): G1 16 04 91264 002 VALID UNTIL: 2017-09-17

START OF CE-MARKING: 2008-5-26

PLACE, DATE OF ISSUE: SHENZHEN, 2016.9.2

SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE