

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: **Patient Monitor/ iM8, M8, iM8A, M8A, iM8B, M8B**
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/AC:2010, IEC 60601-2-27:2011, IEC 80601-2-30: 2009, IEC 60601-2-34:2011, IEC 60601-2-49:2011, ISO 80601-2-61:2011, ISO 80601-2-55:2011, ISO 80601-2-56:2009, ISO 81060-2: 2009, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 14155:2011, EN ISO 14971:2012, EN 62304:2006, EN 62366:2008, EN 980: 2008, EN 1041:2008, EN ISO 780:1999

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: 2007-07-30
PLACE, DATE OF ISSUE: SHENZHEN, 2016.8.2

SIGNATURE: 
NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE