



**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: **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 60601-1-2:2015, EN 60601-1-8:2007/AC:2010, EN 60601-2-27:2014, EN 80601-2-30:2010, EN 60601-2-34:2014, EN 60601-2-49:2015, EN ISO 80601-2-61:2011, EN ISO 80601-2-55:2011, EN ISO 80601-2-56:2012, EN ISO 81060-2: 2014, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 14971:2012, EN 62304:2006, EN 62366:2008, EN 15223-1: 2016, EN 1041: 2008+A1:2013, EN ISO 780:2015**

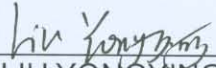
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER **CE** 0123

(EC) CERTIFICATE(S): G1 091264 0006 REV. 01 VALID UNTIL: 2022-09-17

START OF CE-MARKING: 2007-07-30

PLACE, DATE OF ISSUE: SHENZHEN, 2018.12.18

SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE