EDAN INSTRUMENTS, INC.

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
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SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE