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 (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 Ⅱb, 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 DIRECTIVE 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 60601-1-6: 2010+A1: 2015, EN 60601-1-8:2007+A1:2013, EN 62304: 2006+A1:2015, EN 62366-1: 2015, EN 60601-2-49:2015, EN ISO 80601-2-61:2011, EN ISO 80601-2-55:2011, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 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	0123
(EC) CERTIFICATE(S):	G1 091264 0006 REV. 01 VALID UNTIL: 2022-09-17
START OF CE-MARKING:	2008-5-26
PLACE, DATE OF ISSUE:	SHENZHEN, 2019.8.8
SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE