

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: **Vital Signs Monitor / iM3**
The accessories (see Annex 1) 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 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 80601-2-30:2010+A1:2015, EN ISO 81060-2:2014, EN ISO 80601-2-61:2011, EN ISO 80601-2-56:2012, EN 60601-2-49:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008+ A1:2013, EN ISO 780:2015

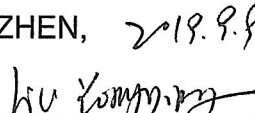
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

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

START OF CE-MARKING: 2017-08-14

PLACE, DATE OF ISSUE: SHENZHEN, 2019.9.8.

SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

ANNEX 1

THE ACCESSORIES USED TOGETHER WITH THE PRODUCT Vital Signs Monitor / iM3 IN EC
DECLARATION OF CONFORMITY

Applied Part	Part Number	Manufacturer	Class
SpO2			
SH1-D Adult Reusable SpO2 Sensor (DB9)	02.01.210120	EDAN	II b
SH3 Neonate Wrap SpO2 Sensor	02.01.210673	EDAN	II b
SH4 Adult Silicone Soft-tip SpO2 Sensor	02.01.210122	EDAN	II b
SH5 pediatric Silicone Soft-tip SpO2 Sensor	02.01.210121	EDAN	II b
SH6 SpO2 Sensor, Ear Clip, Adult/Pediatric, 1 m, reusable	02.57.225000	EDAN	II b
SHD-A SpO2 Sensor, adult, disposable	01.57.471235	EDAN	II b
SHD-P SpO2 Sensor, pediatric, disposable	01.57.471236	EDAN	II b
SHD-I SpO2 Sensor, Infant, disposable	01.57.471237	EDAN	II b
SHD-N SpO2 Sensor, Neonate, disposable	01.57.471238	EDAN	II b
SHD-A SpO2 Sensor, adult, disposable	01.57.471746	EDAN	II b
SHD-P SpO2 Sensor, pediatric, disposable	01.57.471747	EDAN	II b
SHD-I SpO2 Sensor, Infant, disposable	01.57.471748	EDAN	II b
SHD-N SpO2 Sensor, Neonate, disposable	01.57.471749	EDAN	II b
Temp			
Temperature Probe, Oral/Axillary, FT10	02.01.110131	EDAN	II a
Temperature Probe, Rectal, FT20	02.01.110130	EDAN	II a

SIGNATURE: *Qin Zhao* 2019.9.9
NAME: QINZHAO

TITLE: PRODUCT LINE MANAGER