

**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: **Electrocardiograph / SE-301**
iSE-301
The accessories are used together with the product

UMDNS [NAME/CODE]: Interpretive multichannel electrocardiograph / 16231
CLASSIFICATION: Class II a, 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 60601-1-6:2010+A1:2015, EN 60601-2-25:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14155:2011, EN ISO 14971:2012, EN 62304:2006+A1:2015, EN 62366-1:2015, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 780:2015

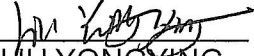
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER  0123

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

START OF CE-MARKING: 2015-09-30

PLACE, DATE OF ISSUE: SHENZHEN, 2018.2.26

SIGNATURE: 
NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE