

## 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-1, SE-100**  
*The accessories are used together with the product*

GMDN [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 60601-1-2:2007/AC: 2010, EN 60601-2-25:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 14155:2011, EN ISO 14971:2012, EN 62304:2006, EN 62366:2008, EN 980:2008, EN 1041:2008, EN ISO 780:1999**

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

IDENTIFICATION NUMBER  0123

(EC) CERTIFICATE(S): G1 17 05 91264 006 VALID UNTIL: 2022-09-17

START OF CE-MARKING: 2005-01-25

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SIGNATURE:

  
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE