



## 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: **Holter System / SE-2003  
SE-2012**

*The accessories are used together with the product*

Holter System Analysis Software  
Holter System Recorder

GMDN [NAME/CODE]: Electrocardiographic Holter analyser / 36827

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  
60601-2-47:2015, 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

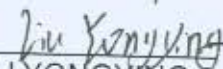
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER: **CE**<sub>0123</sub>

(EC) CERTIFICATE(S): G1 16 04 91264 002 VALID UNTIL: 2017-09-17

START OF CE-MARKING: 2015.07.14

PLACE, DATE OF ISSUE: SHENZHEN, 2017.3.1

SIGNATURE:   
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE