

## 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:** **Fetal Monitor/ F2, F3**  
*The accessories are used together with the product*

**GMDN [NAME/CODE]:** Foetal cardiac monitor / 43958

**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 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, EN 60601-1-6: 2010, EN 60601-1-8: 2007, EN 60601-2-37:2008, EN ISO14971:2012, EN ISO10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN 62304:2006, EN 62366:2008, EN 980: 2008, EN 1041: 2008

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

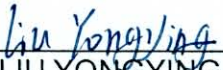
**IDENTIFICATION NUMBER**  0123

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

**START OF CE-MARKING:** 2009-12-27

**PLACE, DATE OF ISSUE:** SHENZHEN, 2016.9.2

**SIGNATURE:**

  
NAME LIU YONGYING  
MANAGEMENT REPRESENTATIVE