

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**

MANUFACTURER: Edan Instruments, Inc.
3/F - B, Nanshan Medical Equipments Park, Nantai
Rd 1019#, shekou, Nanshan Shenzhen, 518067 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 used together with the product is also in the scope of declaration

GMDN [NAME/CODE]: Fetal Monitors /12610

CLASSIFICATION: Class II b, Rule 10 According To Annex IX of the
MDD

CONFORMITY ASSESSMENT ROUTE: Annex II.3

WE 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.

HARMONISED STANDARDS APPLIED: EN 60601-1:2006/AC:2010, EN 60601-1-2: 2007, EN 60601-1-4: 1996+A1:1999, EN 60601-1-6: 2007, EN 60601-1-8: 2007, EN 60601-2-37:2008, EN 61157:2007, EN ISO14971:2009, EN ISO10993-1:2009, EN 62304:2006, EN 980: 2008, EN 1041: 2008

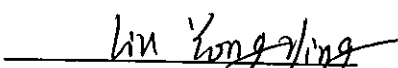
NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 

(EC) CERTIFICATE(S): G1 12 07 44180 024 VALID UNTIL: 2017-09-17

START OF CE-MARKING: 2009-12-27

PLACE, DATE OF ISSUE: SHENZHEN, 2012.9.17

SIGNATURE: 
NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE