EDAN INSTRUMENTS,INC.

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, Nanhai 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: MDD	Class IIb, Rule 10 According To Annex IX OF the
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	CE 0123
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SIGNATURE:	Liu Yongying NAME LIU YONGYING MANAGEMENT REPRESENTATIVE