

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
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: **Vital Signs Monitor / M3A**
The accessories used together with the product is also in the scope of declaration

GMDN [NAME/CODE]: Physiologic Monitoring Systems / 12636

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.

STANDARDS APPLIED: EN 60601-1:1990+A1:1993+A2:1995, EN 60601-1-2: 2007, EN 60601-1-4: 1996+A1:1999, EN 60601-1-6: 2007, EN 60601-1-8: 2007, EN ISO9919:2009, EN 60601-2-30:2000, EN1060-1:1995 +A1: 2002, EN 1060-3:1997+A1: 2005, EN 1060-4:2004, EN 12470-4:2000+A1:2009, EN 62304:2006, EN ISO 10993-1:2009, EN ISO14971:2009, EN 980: 2008, EN 1041: 2008, ANSI/AAMI SP10:2002

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: 2008-5-26

PLACE, DATE OF ISSUE: SHENZHEN,

SIGNATURE:


NAME LIU YONGYING 2012.09.18
MANAGEMENT REPRESENTATIVE