



**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: **Veterinary Monitor/ iM60 VET, iM70 VET**
The accessories are used together with the product

GMDN [NAME/CODE]: Physiologic monitoring systems/12636

CLASSIFICATION: Class I , Rule 1 According To Annex IX OF the MDD

CONFORMITY ASSESSMENT ROUTE: Annex VII


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 60601-1-8:2007/AC:2010, IEC 60601-2-27:2011, IEC 80601-2-30: 2009, IEC 60601-2-34:2011, IEC 60601-2-49:2011, ISO 80601-2-61:2011, ISO 80601-2-55:2011, ISO 80601-2-56:2009, ISO 81060-2: 2013, 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

IDENTIFICATION NUMBER **CE**

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SIGNATURE: 
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MANAGEMENT REPRESENTATIVE