

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: Video Colposcope / C3A, C6A, C6A HD, C300A, iHC3A
The accessories are used together with the product

GMDN [NAME/CODE]: Colposcope /10960

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

CONFORMITY ASSESSMENT ROUTE: Annex II.3

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 62304:2006/ AC:2008, EN 62366:2008, EN ISO 14971:2012, EN 980: 2008, EN 1041: 2008**

IDENTIFICATION NUMBER



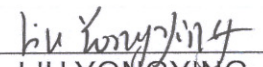
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SIGNATURE:


NAME LIU YONGYING

MANAGEMENT REPRESENTATIVE