# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

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| MANUFACTURER: | Edan Instruments, Inc.<br>#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,<br>Pingshan District, 518122 Shenzhen, P.R.China |
| EUROPEAN REPRESENTATIVE: | Shanghai International Holding Corp. GmbH (Europe)<br>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**

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| SIGNATURE: | Liu Yongying<br>NAME LIU YONGYING<br>MANAGEMENT REPRESENTATIVE |