

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 2007/47/EEC CONCERNING MEDICAL DEVICES

SYC/JY-CE04-0001

Edition C/0



MANUFACTURER: **JIANGSU SUYUN MEDICAL MATERIALS CO., LTD**
NO.18 JIN QIAO ROAD, DAPU INDUSTRIAL PARK, LIANYUNGANG, JIANGSU PROVINCE, PEOPLE'S REPUBLIC OF CHINA, POSTAL CODE:222002

MEDICAL DEVICE: **STERILE VAGINAL SPECULUM FOR SINGLE USE**
CODE:410220,410228,410233,4102MIX,4108MIX,4106MIX,4101MIX

CLASSIFICATION - ANNEX IX: *CLASS I STERILE, RULE 5*

CONFORMITY ASSESSMENT ROUTE: *ANNEX V+ VIII*

WE, JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO13485:2016,EN ISO 14971:2012,EN ISO 11135-1:2007,EN ISO 11607-1:2017,EN ISO 11607-2:2017,EN ISO 10993-1:2009/AC: 2010,EN ISO 10993-5:2009,EN ISO 10993-7:2008/AC: 2009,EN ISO 10993-10:2013,EN 1041:2008,EN ISO 15223-1:2016,EN 1422:2014,EN ISO 11737-1:2018,EN ISO 14155:2011, EN ISO 11138-2:2017

NOTIFIED BODY: **TÜV SÜD PRODUCT SERVICE GMBH**
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S): **GCQ 066729 0004 REV.01**



EUROPEAN REPRESENTATIVE: **Shanghai International Holding Corp. GmbH**
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START OF CE-MARKING: **14.04.2004**

PLACE, DATE OF DECLARATION: **LIANYUNGANG, JIANGSU 2024-4-23**
SIGNATURE:

江苏苏云医疗器材有限公司
JIANGSU SUYUN MEDICAL MATERIALS CO., LTD.
NAME: **ZHANG QINGJUN**
POSITION: **GENERAL MANAGER**
秦宏平