

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

SYC/JY-CE28-0001

Edition:C/0



MANUFACTURER:

JIANGSU SUYUN MEDICAL MATERIALS Co., LTD

No.1 MEDICINE LANE, RENMIN ROAD.222002 LIANYUNGANG, PEOPLE'S REPUBLIC OF CHINA
No.18 JINQIAO ROAD OF DAPU ECONMIC DEVELOPMENT ZONE, LIANYUNGANG, CHINA

MEDICAL DEVICE:

STERILE GYNAECOLOGICAL COLLECTORS FOR SINGLE USE

CERVICAL RAMBRUSH---CODE420211, CERVICAL RAMBRUSH BALL---CODE420222
CERVICAL SPOON---CODE420501 CERVIX BRUSH PLUSH---CODE420151 CERVIX CELL BRUSH---CODE477701-IIID
SPATULA WOODEN---CODE 425002, CERVICAL SPATULA----CODE420301-IIIB3,CODE420311-IIIB4
ENDOMETRIAL SUCTION CURETTE-----CODE420411 (ONE HOLE) CODE420414(FOUR HOLES)

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

 0123

(EC) CERTIFICATE(S):

G2S 043337 0044 Rev.03



EUROPEAN REPRESENTATIVE:

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START OF CE-MARKING:

DATE OF FIRST CE MARKING
17.06.2005

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU; 18.09.2019

SIGNATURE:


JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD

NAME: QIN HONGPING

POSITION: BOARD OF CHAIRMAN