

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

Edition: B/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 Otolaryngological Set for single use
CODE488801 488802

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): G2S 043337 0044 Rev.03



EUROPEAN REPRESENTATIVE: *Shanghai International Holding Corp. GmbH (Europe)*
Eiffestrasse, 80, D-20537, Hamburg, Germany Tel: 0086-021-65951371, 0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING: *DATE OF FIRST CE MARKING*
16.11.2009

PLACE, DATE OF DECLARATION: LIANYUNGANG, JIANGSU; 18.09.2019

SIGNATURE:

江苏苏云医疗器材有限公司
JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD
NAME: *QIN HONGPING*
POSITION: *(PRESIDENT)*