

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION 2017/745

CONCERNING MEDICAL DEVICES

SYC/JY-CE69-0001

Edition: A/0



MANUFACTURER:

NAME: JIANGSU SUYUN MEDICAL MATERIALS Co., LTD.
ADDRESS: NO.18 JIN QIAO ROAD, DAPU INDUSTRIAL PARK,
LIANYUNGANG, JIANGSU PROVINCE, PEOPLE'S REPUBLIC OF CHINA
POSTAL CODE:222002
SRN:CN-MF-000021132

MEDICAL DEVICE:

NAME:STERILE OTOLARYNGOLOGICAL SET FOR SINGLE USE
TYPE AND SIZE:S-1,S-2,M-1,M-2,L-1,L-2,SM,SM-1,SM-2,SM-3.
CODE:488801,488802
Intended purpose: THE MAIN CLINICAL USAGE IS TO INSPECT DISEASES OF ENT.
BASIC UDI-DI:69332982069
CLASSIFICATION - ANNEX VIII: RULE 5: CLASS I, STERILE
CONFORMITY ASSESSMENT ROUTE: ANNEX IX(CHAPTER I + III)

WE, JIANGSU SUYUN MEDICAL MATERIALS Co.,LTD., HERewith DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE MEDICAL DEVICE REGULATION RUGULATION 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017.WE STATED THAT THE EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF OUR COMPANY.

STANDARDS APPLIED: **EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 11135:2014/A1:2019, EN ISO 11607-1:2020/A1:2023,EN ISO 11607-2:2020/A1:2023, EN ISO 10993-1:2020, EN1422:2014, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, MEDDEV2.7.1 REV 4, EN ISO15223-1:2021.**

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRASSE 65, 80339 MUNICH, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No.G11 066729 0008 REV.00



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany
Tel: 0049-40-255726

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU

DATE: 2025-05-26

江苏苏云医疗器材有限公司
JIANGSU SUYUN MEDICAL MATERIALS CO.,LTD.

SIGNATURE:

NAME: ZHANG QINGJUN
POSITION: GENERAL MANAGER