

# DECLARATION OF CONFORMITY MEDICAL DEVICE REGULATION 2017/745 CONCERNING MEDICAL DEVICES

**SYC/JY-CE12-0001**

**Edition: A/0**



MANUFACTURER: *NAME:* JIANGSU SUYUN MEDICAL MATERIALS CO., LTD.

SRN: CN-MF-000021132

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222002 LIANYUNGANG, JIANGSU PROVINCE,  
PEOPLE'S REPUBLIC OF CHINA  
POSTAL CODE: 222002

MEDICAL DEVICE: *NAME:* NON STERILE TONGUE DEPRESSOR

*TYPE AND / OR MODEL:* ADULT      *PRODUCT CODE:* 72522      *BASIC UDI-DI:* 69332982065

*INTENDED PURPOSE:* NON STERILE TONGUE DEPRESSOR IS INTENDED FOR THE INSPECTION OF ORAL DISEASES.

CLASSIFICATION - *ANNEX VIII:*      CLASS I , RULE 5

CONFORMITY ASSESSMENT ROUTE: *ANNEX II + ANNEX 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 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 20417:2021, EN ISO 15223-1:2021,**



EUROPEAN REPRESENTATIVE:

**Shanghai International Holding Corp. GmbH (Europe)**  
**Eiffestrasse, 80, 20537, Hamburg, Germany Tel: 00489-40-**  
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SRN: **DE-AR-000000001**

PLACE, DATE OF DECLARATION:

LIANYUNGANG, JIANGSU

DATE: 2023-6-9

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

SIGNATURE:

张宏平

NAME: ZHANG QINGJUN

POSITION: GENERAL MANAGER