

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

SYC/JY-CE65-0001

Edition: A/1



**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 TONGUE DEPRESSOR*  
TYPE: Adult-I Type, Adult-II Type, Child Type, Infant Type.  
CODE: 72521, 72522, 72523  
Intended purpose: *THE MAIN CLINICAL USAGE IS TO INSPECT ORAL DISEASES ETC.*  
BASIC UDI-DI: 69332982065  
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: 2025-05-22

**SIGNATURE:**

江苏苏云医疗器材有限公司  
NAME: ZHANG QINGJUN  
POSITION: GENERAL MANAGER

秦宏平