

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: Changzhou Shuangma Medical Devices Co.,Ltd
220 Sanhe Road, Zhenglu, Tianning, 213115 Changzhou, Jiangsu, China

SRN: CN-MF-000009732

Trademark: 

Name and address European Representative: Llins Service & Consulting GmbH
Heinigstrasse 26, 67059 Ludwigshafen, Germany

SRN: DE-AR-000009077

Product Name Vaginal Speculums for Single Use

Product Model: Side screw type, Spanish type, French type

Basic UDI-DI: 69451447006KZQ6T

EMDN Code: U089006

Classification acc. to MDD Ax. IX: Class Is, rule 5

Applied Standard: EN ISO 14971:2019; EN ISO 10993-1:2020
EN ISO 20417: 2021; EN ISO15223-1:2021
EN ISO 13485:2016;

Conformity assessment procedure: Annex V of MDD

CE certificate no.: 6054198CN

Issue date: 2025.1.21

Valid until: 2029.2.1

Name, address and ID of the Notified Body: DEKRA Certification B.V.
Meander 1051, 6825 MJ Arnhem, P.O. Box 5185, 6802 ED Arnhem, The Netherlands



We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer. The device is considered as legacy device and application for extended validity in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 has been done.

Changzhou, 2024-12-05

Changzhou, 2024-12-05

Place, date

Xu aiping, General manager

Xu aiping, General manager

Name and function