

Declaration of Conformity

Manufacturer **Yuhuan County Shengbo Mould Manufacturing Co., Ltd.
Western of Chinese Sterile Medical Equipment
Base, Qinggang Town, Yuhuan County, Zhejiang Province,
China.**

European Representative **KINGSMEAD SERVICE LIMITED
145-157 St John Street, London, EC1V 4PY (UK)**

Product Name: **Disposable vaginal speculum**

Type: **S, M, L**

UMDNS Code: **11267**

Classification (MDD, Annex IX): **I sterile, rule 5**

Conformity Assessment Route: **Annex V.**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: **TÜV SÜD Product Service GmbH, Ridlerstr.
65, 80339 München, Germany**

NB Identification number: **0123**

(EC) Certificate(s):

Expire date of the Certificate:

Start of CE Marking:

Place, Date of Issue: **Yuhuan, 2015-12-15**

Signature:

Name: **Alan Zhou**

Position: **General Manager**

**EC Declaration of Conformity
ShengboCE2-01(A/0)**

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