

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 Prolinx GmbH
Representative Brehmstr. 56, 40239, Duesseldorf
Dimdi code: DE/0000045300

Product Name: Disposable vaginal speculum

REF: 47541、70934、70935、70936、70937、47215、
47214、46084、47848、47849、47850

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): G2S 094018 0009 Rev.01

Expire date of the Certificate: 26 May, 2024

Start of CE Marking: 2 Feb, 2021

Signature:

Name:

陈财强

Position: **General Manager**

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ShengboCE2-01(A/0)

