Declaration of Conformity

Manufacturer	**YUHUAN CITY SHENGBO MOULD MANUFACTURING CO.,LTD.** WESTERN OF CHINESE STERILE MEDICAL EQUIPMENT BASE, QINGGANG TOWN,317606,YUHUAN CITY,ZHEJIANG PROVINCE,PEOPLE'S REPUBLIC OF CHINA
European Representative :	**Prolinx GmbH** **Brehmstr. 56, 40239, Duesseldorf** **Dimdi Code:DE/0000045300**
Product Name:	Gynecologial set
Type:	S, M, L,XL
UMDNS Code:	11314

Classification (MDD, Annex IX):**class Is, 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.The manufacturer is exclusively responsible for the DOC.

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):	G2 S094018 0009 Rev.01
Expire date of the Certificate:	2024.05.26
Start of CE Marking:	**2016-03-15**
Place, Date of Issue:	**Yuhuan, 2021-2-3**

Signature:

Name: **Chen caineng**

Position: **General Manager**