Declaration of Conformity

Manufacturer: Changzhou Jiafeng Medical Equipment Co., Ltd.

Zhongjiang Village, Sanhekou Zhenglu Town, Wujin District 213115 Changzhou City, Jiangsu Province PEOPLE'S REPUBLIC

OF CHINA

European Repre- Shanghai International Holding Corp. GmbH (Europe)

sentative: Eiffestrasse 80,20537 Hamburg, GERMANY

Product Name Sterile Syringes Irrigating

Model Number: 100ml, 150ml

UMDNS/GMDN

13942

Code:

Classification (MDD, Annex IX): Ila, rule 6

Conformity Assessment Route: Annex V.3 of MDD

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. This declaration of conformity is our sole responsibility.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,

80339, München, Germany

Identification number: CE0123

Place, Date of Issue: Changzhou, 2020-5-17

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Signature:

Name: Mr. Jinde Wu

Position: General Manager

Changahou Jiafeng Medical Equipment Co., Ltd

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