

Declaration of Conformity

Manufacturer: **Changzhou Jiafeng Medical Equipment Co., Ltd.**
Ninghe Village, Zhenglu Town, Tianning District, Changzhou
City, 213115 Jiangsu Province, PEOPLE'S REPUBLIC OF
CHINA

European Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80,20537 Hamburg, GERMANY

Product Name **Sterile Hypodermic Syringes for Single Use (with Needle)**

UMDNS Code: **13940**

MODELS: **1ml, 2ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 30ml, 50ml**
0.3mm, 0.33mm, 0.4mm, 0.45 mm, 0.5 mm, 0.55 mm,
0.6 mm, 0.7 mm, 0.8 mm, 0.9 m, 1.1 m, 1.2 mm

Classification (MDD, Annex IX): **Ila, rule 6**
Conformity Assessment Route: **Annex V.3**

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. We are exclusively responsible for the declaration of conformity.

EUROPEAN STANDARDS AND INTERNATIONAL STANDARDS

ISO 7886-1:2017, ISO 14971: 2007, ISO 11135:2014, EN 980:2016, EN 1041:2016, ISO 10993-1:2018, 93/42/EEC, 2007/47/EC, ISO 11607-1,2:2019, ISO13485:2016, ISO 11737-1:2018, ISO 10993-4:2017, ISO10993-5:2009, ISO10993-7:2008, ISO10993-10:2010, ISO10993-11:2017, MEDDEV 2.7.1, ISO 7864:2016

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

(EC) Certificate(s): **G2 072857 0013 Rev.00**

Expire date of the Certificate: **2024-05-26**

Start of CE Marking: **2010-12-21**

Place, Date of Issue: **Changzhou, 2023-01-02**

Signature:



Name: **Mr.Chengmin Luo**

Position: **Management representative**

