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)**
GMDN Code:	35904

Classification (MDD, Annex IX): **IIa, 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 8537:2016, 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:	**2028-12-31**
Start of CE Marking:	**2010-12-21**
Place, Date of Issue:	**Changzhou, 2024-05-03**

Signature: _____

Name: **Mr.Chengmin Luo**

Position: **Management representative**

CHANGZHOU JIAFENG MEDICAL EQUIPMENT CO., LTD 常州市佳峰医疗器材有限公司