## **Declaration of Conformity**

Manufacturer: Changzhou Chuangjia Medical Appliance Co., Ltd.

Sanhekou Development Zone, Zhenglu Town213115, Changzhou, China

European Lotus NL B.V.

Representative: Koningin Julianaplein 10, 1 e Verd,

2595AA, The Hague, Netherlands.

Product Name Sterile syringes for single use

Model Number: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml

UMDNS Code: 13940

Classification (MDD, Annex IX): Ila, rule 2

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

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München,

Germany

Identification number:  $\bigcup_{0.023}$ 

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(EC) Certificate(s): G2 076830 0008 Rev.02

Expire date of the Certificate: 2024-05-26

Place, Date of Issue MEDICA Changzhou, 2021-03-19

Signature:

Name: Mr. Jia Xu

Position: General Manager