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## Declaration of Conformity

**Manufacturer: First Global Enterprises Limited**

**Address:** Suite2006, 20th Floor, 340 Queen's Road, Central, Hongkong

**Authorized European Representative:** Shanghai International Holding Corp. GmbH (Europe)

**Address:** Eiffestraße 80 20537 Hamburg GERMANY

**Medical Device:**

**-Model Name:** Irrigation Syringe

**-Type or size:** 60ml, 100ml

**-Classification:** I Sterile (Rule 2, Annex IX, MDD 93/42/EEC (2007))

**-UMDNS Code:** UMDNS 15-256

**-Conformity Assessment Procedure:** Annex V

We herewith declare in our sole responsibility that the above mentioned product(s) meet(s) 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 declaration of conformity is issued under our sole responsibility.

### DIRECTIVES

**General Applicable Directives:**

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC.

**Notified Body:** TÜV SÜD Product Service GmbH

**Address:** Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany.

**Identification No.:** CE0123

**EC Certificate(s):** G2S 079702 0022 Rev.01

**EC certificate(s) valid until:** 2024-05-26

**Start of CE Marking:** 2017

Suite 2006, 20th Floor, 340 Queen's Road Central,  
Sheung Wan, Hong Kong

(Place and date of issue)\* 2020-06-02



(Signature and title of authorized person)\*