

Zhejiang Longde Pharmaceutical Co.,Ltd.	CE Technical Document
Declaration of Conformity	Document No.: Q/LDOI41-01-10
	Control Status: Rev.2

Declaration of Conformity

Manufacturer: Zhejiang Longde Pharmaceutical Co.,Ltd.

Address: No.510 Shunfeng Road, Qianjiang Economic Development Zone, 311106, Hangzhou, Zhejiang, P.R.China

European Representative: Obelis s.a.

Address: Bd. Général Wahis 53, 1030 Brussels, Belgium.

Product: Sterile Hypodermic Syringes For single Use

Model Code: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml

Classification (MDD, Annex IX): II a

Classification Rule: Rule 6

UMDNS Code: 13940

Conformity Assessment Route: MDD 93/42/EEC 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.

Zhejiang Longde Pharmaceutical Co.,Ltd is exclusively responsible for the declaration of conformity.

DIRECTIVES

General Applicable Directive:

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Notify Body: TUV SUD Product Service GmbH, Ridlerstr.65, 80339 Munich, Germany

NB Identification number: 0123

(EC) Certificate(s) No.: G2 043616 0024 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2002-06-10

Place, of Issue: Qianjiang Economic Development Zone, Hangzhou.

Signature: Jianping Lu

Mr. Jianping Lu

General Manager
Date: 2020. 4. 3

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Label Code	Description(EN)
313001	SOL-M 2ml Syringe w/o Needle, 2-piece
307005	SOL-M 5ml Syringe w/o Needle, 2-piece
308003	SOL-M 10ml Syringe w/o Needle, 2-piece
309003	SOL-M 20ml Syringe w/o Needle, 2-piece