

Declaration of Conformity

Manufacturer: Zhejiang Longde Pharmaceutical Co.,Ltd

Address: No.510 Shunfeng Road, Linping District 311106 Hangzhou, Zhejiang PEOPLE'S
REPUBLIC OF CHINA

Product name: Sterile Hypodermic Syringes for Single Use

Model/Type/Size: 1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml,60ml

Classification (MDR, Annex VIII Rule 2): I s

Classification Rule: Rule 2

EMDN Code: A020102010102、 A020102010202、 A02010202、 A020102020102

Manufacturer SRN: CN-MF-000021623

Basic UDI-DI: 697096986063P

European Representative: Obelis s.a.

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

Authorized representative SRN: BE-AR-000000106

Conformity Assessment Route: MDR 2017/745 Annex XI.

We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL of 5 April 2017

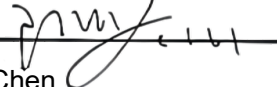
Notify Body: TUV SUD Product Service GmbH, Ridlerstr.65, 80339 Munich, Germany

NB Identification number: 0123

(EC) Certificate(s): No.G21 043616 0030

Expire date of the Certificate: 2030-02-23

Place, of Issue: Hangzhou, Zhejiang.

Signature: 

Mrs. Qinli Chen

General Manager

Date: 2025.04.15

Product Appendix

Product name	Model/Type/Size	Classification	Classification Rule	Intended use	LD Ref Number	LD Product Description	Sol-M Ref Number	Sol-M Product Description
SOL-M 2ml Syringe w/o Needle, 2-piece	2ml	Is	Rule 2	This device intended to inject fluids into, or withdraw fluids from the body.	HS2Z02	Sterile Hypodermic Syringes for Single Use LUER SLIP, 2-PIECES W/O NEEDLE 2ML	313001	SOL-M 2ml Syringe w/o Needle, 2-piece
SOL-M 5ml Syringe w/o Needle, 2-piece	5ml				HS2Z05	Sterile Hypodermic Syringes for Single Use LUER SLIP, 2-PIECES W/O NEEDLE 5ML	307005	SOL-M 5ml Syringe w/o Needle, 2-piece
SOL-M 10ml Syringe w/o Needle, 2-piece	10ml				HS2Z10	Sterile Hypodermic Syringes for Single Use LUER SLIP, 2-PIECES W/O NEEDLE 10ML	308003	SOL-M 10ml Syringe w/o Needle, 2-piece
SOL-M 20ml Syringe w/o Needle, 2-piece	20ml				HS2Z20	Sterile Hypodermic Syringes for Single Use LUER SLIP, 2-PIECES W/O NEEDLE 20ML	309003	SOL-M 20ml Syringe w/o Needle, 2-piece