EU Declaration of conformity

Product name: Sterile syringes without needle for single use

Document Revision History

REV.	Description	Originator	Date
A/0	Initial release, MDR file.	Huangjiahui	2020-8-13
A/1	Update according MDR Annex IV	Huangjiahui	2020-9-30
A/2	Add SRN number	Yuhaiyu	2021-6-30
A/3	Update the standard	Huangjiahui	2022-8-22
A/4	Update certificate information	Lizhan	2022.9.29
A/5	Add type 4: PC syringe specification Add type 5、6: two-parts syringe	Lizhan	2022-11-16
A/6	Update certificate information	Lizhan	2023-8-9
A/7	Update Package type and materials	Lizhan	2024-9-3
A/8	Update Basic UDI-DI	Pengmengmeng	2024-12-9
A/9	Add enterprise standard of two-parts syringe	Pengmengmeng	2025-3-5
A/10	Update certificate information and standards.	Pengmengmeng	2025-5-6
A/11	Detailed description of the classification rules; Add the address of the signatory; Modify Conformity assessment Route.	Pengmengmeng	2025.8.4
A/12	Update the CE certificate information and the version of the enterprise standard.	Pengmengmeng	2026.1.9

EU Declaration of conformity

Manufacturer:	Shanghai Kindly Enterprise Development Group Co., Ltd. No.658 Gaochao Road 201803 Shanghai PEOPLE'S REPUBLIC OF CHINA
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80,20537 Hamburg ,GERMANY
Device name:	Sterile syringes without needle for single use
Device Model Number:	1、Variant 1-Three parts, without needle, luer slip(centre), with/without cap,latex free Syringes variants : 1、2、2.5、3、5、10、20、50、60ml 2、Variant 2-Three parts, without needle, luer slip(side), with/without cap,Latex free Syringes variants : 10、20、25、30、35、50、60ml 3、Variant 3-Three parts, without needle, luer lock, with/without cap,Latex free Syringes variants :1、2、2.5、3、5、10、20、30、35、50、60、100ml 4、Variant 4-PC syringe,three parts, without needle, luer lock, with/without cap,Latex free Syringes variants :1、3、5、10、20、30ml 5、Variant 5-Two parts, without needle, luer slip(centre), with/without cap,Latex free Syringes variants :1ml 6、Variant 6-Two parts, without needle, luer lock, with/without cap,Latex free Syringes variants :1ml 7、Variant 7-Three parts, without needle, luer slip(centre), colored plunger, with/without cap,latex free Syringes variants : 1、2、2.5、3、5、10、20、50、60ml 8、Variant 8-Three parts, without needle, luer slip(side), colored plunger, with/without cap,Latex free Syringes variants : 10、20、25、30、35、50、60ml 9、Variant 9-Three parts, without needle, luer lock, colored plunger,with/without cap,Latex free Syringes variants :1、2、2.5、3、5、10、20、30、35、50、60、100ml 10、Variant 10-PC syringe,three parts, without needle, luer lock, colored plunger, with/without cap,Latex free Syringes variants :1、3、5、10、20、30ml
Device Intended purpose	Sterile syringes without needle are intended to use with a 6% conical fitting device to inject drug for patient, such as hypodermic needles. And syringes are intended for use immediately after filling and are not intended to contain the medicament for extended periods of time.
Basic UDI-DI:	69301978202001s05701ER 69301978202001s05702ET 69301978202201s05703GB
Risk class:	Ⅰm/s (In accordance with Rule 2 of Annex Ⅷ of the MDR (EU) 2017/745.)
Conformity assessment Route:	MDR Annex IX excluding Chapter II
References	EN ISO 7886-1:2018, Q/JKDL-73-2026, MEDDEV.2.7.1 Rev.4,EN ISO 15223-1:2021,ISO 80369-7:2021,EN ISO 11135:2014,EN ISO 11607-1:2020, EN ISO 11607-2:2020,EN ISO 13485:2016,EN ISO10993-1:2020

Statement	We hereby declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer, the products mentioned above is in conformity with the medical device Regulation, All supporting documentations are retained under the premises of the manufacture.
Notified body	Name: TÜV SÜD Product Service Gmbh· Ridlerstraße 65 · 80339 München · Germany
NB Identification number	0123
Manufacturer SRN:	CN-MF-000005652
(EC) Certificate(s)	G15 041808 0065 Rev.01
Device Group	A020102-infusion and irrigation syringes, single use MDS 1005.1-EO Sterile MDS 1010-Device with a measuring function
Valid from	2026-02-11
Valid until	2031-02-10
Date of Initial issuance	2025-04-09
Signature: **Name:** **Position:** **Place:**	Liuhualong Regulations manager No.658 Gaochao Road 201803 Shanghai PEOPLE'S REPUBLIC OF CHINA