

# EU Declaration of conformity

**Product name: Sterile syringes for single use**

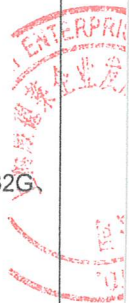
## Document Revision History

REV.	Description	Originator	Date
A/0	Initial release, MDR file.	Huangjiahui	2020-8-12
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, Review and re sign	Lizhan	2022-10-11
A/5	PC syringes added in 3ml, 5ml, 10ml, 20ml, 30ml sizes	Lizhan	2022-11-15
A/6	Update certificate information	Lizhan	2023-8-10
A/7	Update Basic UDI-DI and enterprise standard.	Pengmengmeng	2024-12-12
A/8	Update certificate information and standard.	Pengmengmeng	2025-5-6
A/9	Detailed description of the classification rules; Add the address of the signatory; Modify Conformity assessment Route.	Pengmengmeng	2025.8.4
A/10	Update the CE certificate information and standard.	Pengmengmeng	2026.1.5



## EU Declaration of conformity

<b>Manufacturer:</b>	Shanghai Kindly Enterprise Development Group Co., Ltd. No.658 Gaochao Road 201803 Shanghai PEOPLE'S REPUBLIC OF CHINA
<b>European Representative:</b>	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80,20537 Hamburg ,GERMANY
<b>Device name:</b>	Sterile syringes for single use
<b>Device Model Number:</b>	<p>1、 Variant 1-Three parts, with needle, luer slip(centre),latex free Syringes variants : 1、 2、 2.5、 3、 5、 10、 20、 50、 60ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>2、 Variant 2-Three parts, with needle, luer slip(side), Latex free Syringes variants : 10、 20、 25、 30、 35、 50、 60ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>3、 Variant 3-Three parts, with needle, luer lock, Latex free Syringes variants :1、 2、 2.5、 3、 5、 10、 20、 30、 35、 50、 60、 100ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>4、 Variant 4- PC syringe, three parts, with needle, luer lock, Latex free Syringes variants :1ml, 3ml, 5ml, 10ml, 20ml, 30ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>5、 Variant 5- Sterile syringes (with fixed needle), three parts, with needle, luer slip, Latex free Syringes variants :1ml Needles variants: 23G、 24G、 25G、 26G、 27G、 28G、 29G、 30G、 31G</p> <p>6、 Variant 6- Three parts, with needle, luer slip(centre), colored plunger,latex free Syringes variants : 1、 2、 2.5、 3、 5、 10、 20、 50、 60ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>7、 Variant 7- Three parts, with needle, luer slip(side), colored plunger,Latex free Syringes variants : 10、 20、 25、 30、 35、 50、 60ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>8、 Variant 8- Three parts, with needle, luer lock,colored plunger, Latex free Syringes variants :1、 2、 2.5、 3、 5、 10、 20、 30、 35、 50、 60、 100ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>9、 Variant 9- PC syringe,three parts, with needle, luer lock,colored plunger, Latex free Syringes variants :1、 3、 5、 10、 20、 30ml Needles variants: 18G、 20G、 21G、 22G、 23G、 25G、 26G、 27G、 28G、 29G、 30G、 31G、 32G、 33G</p> <p>10、 Variant 10- Sterile syringes (with fixed needle),three parts, with needle, luer slip, colored plunger,Latex free Syringes variants :1ml Needles variants: 23G、 24G、 25G、 26G、 27G、 28G、 29G、 30G、 31G</p>
<b>Device Intended purpose</b>	Sterile syringes with needle are intended to inject drug for patient. And syringes are intended to use immediately after filling and are not intended to contain the medicament for extended periods of time.



<b>KDL</b>	Document name	EU Declaration of conformity	Document No.:	KDL/TECH-MDR-04/00	
	Product name	Sterile syringes for single use	Version	A/10	Page 3 of 3

<b>Basic UDI-DI:</b>	69301978202002a004016E 69301978202002a004026G 69301978202002a004036J
<b>Risk class:</b>	IIa (In accordance with Rule 6 of Annex VIII of the MDR (EU) 2017/745.)
<b>Conformity assessment Route:</b>	MDR Annex IX excluding Chapter II
<b>References</b>	EN ISO 7886-1:2018, Q/JKDL-04-2019,ISO 80369-7:2021, EN ISO 15223-1:2021,EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 13485:2016, EN ISO10993-1:2020
<b>Statement</b>	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.
<b>Notified body</b>	Name: TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Germany
<b>NB Identification number</b>	0123
<b>Manufacturer SRN:</b>	CN-MF-000005652
<b>(EC) Certificate(s)</b>	G15 041808 0066 Rev.01
<b>Device Group</b>	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances,including devices for dialysis
<b>Valid from</b>	2026-02-11
<b>Valid until</b>	2031-02-10
<b>Date of Initial issuance</b>	2025-04-09
<b>Signature:</b>	
<b>Name:</b>	
<b>Position:</b>	
<b>Place:</b>	
	Liuhualong Regulations manager No.658 Gaochao Road 201803 Shanghai PEOPLE'S REPUBLIC OF CHINA
	Rev.20260105