



E013: Injection devices for therapeutic purposes



Product name:	SHIFA syringe 1ml
IMD-PQS Code:	E013-128
Status:	Prequalified
Date of acceptance:	20 Oct 2020
Appliance type:	E013
Product description:	RUP syringe 1ml
Manufacturer:	Changzhou Tongda Medical Appliance Co., Ltd
Manufacturers Reference:	SHIFA syringe 1ml
Address:	Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. No. 208, Sanhe Road Changzhou Jiangsu China
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Website address:	http://www.tongdachina.com.cn
Valid until:	31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication variable dose administration	Restrictive use for	None
Graduations (ml)	0.10	Needle Size	Other
Needle Size (Other)	26Gx5/8"	Needle Fixation	Detached
Nominal capacity (ml)	1.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	3.00	RUP mechanism	locked & broken plunger
RUP Type	Plunger lock	Location RUP activation	End of injection
RUP Needle Fixation	Not Fixed	RUP Needle Sizes	26G x 3/8" (10 mm)
RUP Nominal Capacity (ml)	1.00	RUP plunger Aspiration	Multiple
RUP Primary Packaging	Blister pack	RUP Sub-category	Simple RUP
CE marking	Yes		

Comments	Needle at side available Pieces per carton:2000 or 2400
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PRICE AND SHIPPING

Shipping volume (m3)	0.090447	Shipping weight (kg)	12.78
Pieces per package	2000	Minimum order	200000.00
Price 1	price on request	Year of base price	2020
Incoterms	FOB		

QUALITY STANDARD

Quality Standard	ISO 13485	Specification Reference	Applicable PQS specification: ISO 7886-4 Applicable PQS VP(s): ISO 7886-4
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PRODUCT SITES

Organization name	Changzhou Tongda Medical Appliance Co., Ltd
Address	Group 4, Ninghe village, Zhenglu Town, Tianning District Changzhou Jiangsu China

Current PQS status:	Prequalified	Valid until:	31 May 2026
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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.