



E013: Injection devices for therapeutic purposes



Product name:	SHIFA syringe 10ml
IMD-PQS Code:	E013-131
Status:	Prequalified
Date of acceptance:	20 Oct 2020
Appliance type:	E013
Product description:	RUP syringe 10ml
Manufacturer:	Changzhou Tongda Medical Appliance Co., Ltd
Manufacturers Reference:	SHIFA syringe 10ml
Address:	Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. No. 208, Sanhe Road Changzhou Jiangsu China
Telephone:	+86 51988670522
Email:	info@tongdamedical.com
Website address:	http://www.tongdachina.com.cn
Valid until:	31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication fixed dose administration; Medication variable dose administration	Restrictive use for	None
Graduations (ml)	0.50	Needle Size	Other
Needle Size (Other)	22Gx1 1/4"	Needle Fixation	Detached
Nominal capacity (ml)	10.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	3.00	RUP mechanism	locked and broken plunger
RUP Type	Plunger lock	Location RUP activation	End of injection
RUP Needle Fixation	Not Fixed	RUP Needle Sizes	22G x 1 1/4" (30 mm)
RUP Nominal Capacity (ml)	10.00	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: 1600 or 1200
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PRICE AND SHIPPING

Shipping volume (m3)	0.139776	Shipping weight (kg)	18.94
Pieces per package	1600	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

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.