



E013: Injection devices for therapeutic purposes



Product name:	SKIFA RUP 1ml
IMD-PQS Code:	E013-110
Status:	Prequalified
Date of acceptance:	05 Jul 2015
Appliance type:	E013
Product description:	RUP syringe 1ml
Manufacturer:	Mitra Rajawali Banjaran, PT
Manufacturers Reference:	SKIFA RUP 1ml
Address:	JL. Raya Banjaran KM16 Bandung Jawa Barat Indonesia
Telephone:	+62 22 594 0151
Email:	nurasfiahqo@gmail.com
Website address:	http://www.mrb.co.id
Valid until:	31 May 2025

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None
Vaccine capacity (mL)	1.00	Graduations (ml)	0.05
Needle Size	Other	Needle Size (Other)	26G x 1/2 "
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	Hooked to hub at end of injection	RUP Type	Other
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

PRICE AND SHIPPING

Shipping volume (m3)	0.142	Shipping weight (kg)	11.88
Pieces per package	100	Minimum order	10000.00
Price 1	24cts	Year of base price	2015
Incoterms	EXW		

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	Mitra Rajawali Banjaran, PT
Address	JL. Raya Banjaran KM16 Bandung Jawa Barat Indonesia

Current PQS status:	<i>Prequalified</i>	Valid until:	<i>31 May 2025</i>
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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.