



E013: Injection devices for therapeutic purposes



Product name:	Oneject II RUP Syringe 5 mL
IMD-PQS Code:	E013-109
Status:	Prequalified
Date of acceptance:	21 Sep 2015
Appliance type:	E013
Product description:	RUP syringe 5ml
Manufacturer:	PT Oneject Indonesia
Manufacturers Reference:	Oneject II RUP Syringe 5 mL
Address:	Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor Jawa Barat Indonesia
Telephone:	+62 21 879 17 422
Email:	niken.permatasari@oneject.co.id
Website address:	www.oneject.co.id
Valid until:	31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication fixed dose administration	Restrictive use for	Therapeutic use
Graduations (ml)	0.10	Needle Size	Other
Needle Size (Other)	21G x 1 ½"	Needle Fixation	Detached
Nominal capacity (ml)	5.00	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	21G x 1 1/2" (38 mm)
RUP Nominal Capacity (ml)	5.00	RUP plunger Aspiration	Multiple
RUP Primary Packaging	Blister pack	RUP Sub-category	Simple RUP
CE marking	Yes		

PRICE AND SHIPPING

Shipping volume (m3)	0.08	Shipping weight (kg)	12.00
Pieces per package	1200	Minimum order	1200.00
Price 1	Upon request to manufacturer	Year of base price	2015
Incoterms	FOB		

QUALITY STANDARD

Quality Standard	ISO 13485;Other	Quality standard (Other)	ISO 9001
Specification Reference	Applicable PQS specification: ISO 7886-4 Applicable PQS VP(s): ISO 7886-4		

PRODUCT SITES

Organization name	PT Oneject Indonesia
Address	Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor Jawa Barat Indonesia

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.