



E013: Injection devices for therapeutic purposes



Product name:	Oneject K1 3ml
IMD-PQS Code:	E013-019
Status:	Prequalified
Date of acceptance:	05 Jul 2007
Appliance type:	E013
Product description:	RUP syringe 3ml
Manufacturer:	PT Oneject Indonesia
Manufacturers Reference:	Oneject K1 3ml
Country of Manufacture:	Indonesia
Address:	Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor 16810, Indonesia 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 variable dose administration;Medication variable dose reconstitution	Restrictive use for	None
Graduations (ml)	0.10	Needle Size	Other
Needle Size (Other)	23G x 1 1/4"	Needle Fixation	Fixed
Nominal capacity (ml)	3.00	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	Fixed	RUP Needle Sizes	23G x 1" (25 mm)
RUP Nominal Capacity (ml)	3.00	RUP plunger Aspiration	Multiple
RUP Primary Packaging	Blister pack	RUP Sub-category	Simple RUP
CE marking	Yes		

PRICE AND SHIPPING

Shipping volume (m3)	0.11	Shipping weight (kg)	13.60
Pieces per package	1800	Minimum order	18000.00
Price 1	On request to manufacturer	Year of base price	2010
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 16810, Indonesia Indonesia

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.