E013: Injection devices for therapeutic purposes

Product name:	Oneject K1 5ml
IMD-PQS Code:	E013-024
Status:	Prequalified
Date of acceptance:	21 May 2007
Appliance type:	E013
Product description:	RUP syringe 5ml
Manufacturer:	PT Oneject Indonesia
Manufacturers Reference:	Oneject K1 5ml
Country of Manufacture:	Indonesia
Address:	Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor 16810, Indonesia Indonesia
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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)	0.20	**Needle Size**	Other
Needle Size (Other)	21G x 1 1/2"	**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**	Plunger locked and broken
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)	0.09	**Shipping weight (kg)**	11.10
Pieces per package	1200	**Minimum order**	12000.00
Price 1	On request to manufacturer	**Year of base price**	2008
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:	*Prequalified*	**Valid until:**	*31 May 2026*

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.