



E013: Injection devices for therapeutic purposes



Product name:	OnejectII RUP insulin 1ml
IMD-PQS Code:	E013-092
Status:	Prequalified
Date of acceptance:	06 May 2013
Appliance type:	E013
Product description:	RUP syringe 1ml Insulin
Manufacturer:	PT Oneject Indonesia
Manufacturers Reference:	OnejectII RUP insulin 1ml
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 variable dose administration	Restrictive use for	Insulin administration
Graduations (ml)	0.02	Needle Size	Other
Needle Size (Other)	27G x 3/8"	Needle Fixation	Fixed
Nominal capacity (ml)	1.00	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	27G 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)	0.051	Shipping weight (kg)	8.23
Pieces per package	1600	Minimum order	16000.00
Price 1	Upon request to manufacturer	Year of base price	2013
Incoterms	FOB		

QUALITY STANDARD

Quality Standard	ISO 13485	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
----------------------------	--------------	---------------------	-------------

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.