E013: Injection devices for therapeutic purposes

Product name:	**VanishPoint II® Retractable 1 ml**
IMD-PQS Code:	E013-006
Status:	Prequalified
Date of acceptance:	15 Jun 2005
Appliance type:	E013
Product description:	RUP retractable 1ml
Manufacturer:	Retractable Technologies, Inc.
Manufacturers Reference:	VanishPoint II® Retractable 1 ml
Country of Manufacture:	China
Address:	511 Lobo Lane, Little Elm, TX 75068 United States of America
Telephone:	+1 972 294 1010
Email:	kduesman@retractable.com
Website address:	www.retractable.com
Valid until:	31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication variable dose administration	**Restrictive use for**	None
Vaccine capacity (mL)	1.00	**Graduations (ml)**	0.01
Needle Size	Other	**Needle Size (Other)**	27G x 12.7 mm
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	Retraction of needle into barrel by spring	**RUP Type**	Other
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**	Paper blister pack
RUP Sub-category	Retractable RUP		

Comments	The retraction of the needle is a reuse prevention feature (RUP) and a sharp injury Protection (SIP)

PRICE AND SHIPPING

Shipping volume (m3)	0.0432	**Shipping weight (kg)**	4.50
Pieces per package	800	**Minimum order**	800.00
Price 1	On request	**Year of base price**	2005
Incoterms	FCA		

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	Retractable Technologies, Inc.
Address	511 Lobo Lane, Little Elm, TX 75068 United States of America

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.