

WHO Immunisation Devices - Performance, Quality & Safety

E013: Injection devices for therapeutic purposes



VanishPoint II® Retractable 1ml insulin Product name:

IMD-PQS Code: F013-015 Prequalified Status: 15 Jun 2005 Date of acceptance: E013 Appliance type:

Product description: RUP retractable 1ml Insulin Manufacturer: Retractable Technologies, Inc.

Manufacturers Reference: VanishPoint II® Retractable 1ml insulin

Country of Manufacture:

Address: 511 Lobo Lane, Little Elm, TX 75068

United States of America

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Email: kduesman@retractable.com

Website address: www.retractable.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for Insulin administration

administration

Other 1.00 Needle Size Graduations (ml) Needle Size (Other) 29G x 12.7 mm **Needle Fixation** Fixed

Nominal capacity (ml) 1.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration

RUP mechanism **Number of pieces** 3.00 Retraction of needle into barrel

by spring

Yes

RUP Type Other **Location RUP activation** End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 29G 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

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

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

FCA Incoterms

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.