



E013: Injection devices for therapeutic purposes



Product name:	Revital 5ml (2 piece)
IMD-PQS Code:	E013-043
Status:	Prequalified
Date of acceptance:	01 Aug 2009
Appliance type:	E013
Product description:	RUP syringe 5ml
Manufacturer:	Revital Health Care (EPZ) Limited
Manufacturers Reference:	Revital 5ml (2 piece)
Country of Manufacture:	Kenya
Address:	P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239, Takaungu 80100 Mombasa Kenya
Telephone:	+254722412900
Email:	qa@rhcare-epz.com
Website address:	www.revitalhcare.com
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)	21Gx1 ½" (38mm)	Needle Fixation	Detached
Nominal capacity (ml)	5.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	2.00	RUP mechanism	Plunger lock and break
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	Paper blister pack	RUP Sub-category	Simple RUP
CE marking	Yes		

PRICE AND SHIPPING

Shipping volume (m3)	0.128	Shipping weight (kg)	17.60
Pieces per package	2500	Minimum order	500000.00
Price 1	Per unit: 0.0295 US\$	Year of base price	2008
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	Revital Health Care (EPZ) Limited
Address	P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239, Takaungu 80100 Mombasa Kenya

Current PQS status:	<i>Prequalified</i>	Valid until:	<i>31 May 2026</i>
----------------------------	---------------------	---------------------	--------------------

Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.