



## E013: Injection devices for therapeutic purposes



<b>Product name:</b>	Safegard Retractable safety syringe 1ml Tuberculin
<b>IMD-PQS Code:</b>	E013-044
<b>Status:</b>	Prequalified
<b>Date of acceptance:</b>	22 Feb 2010
<b>Appliance type:</b>	E013
<b>Product description:</b>	RUP retractable 1ml Tuberculin
<b>Manufacturer:</b>	Safegard Medical (Hungary) Kft
<b>Manufacturers Reference:</b>	Safegard Retractable safety syringe 1ml Tuberculin
<b>Country of Manufacture:</b>	Hungary
<b>Address:</b>	Jószerecsét tér 15 3608 Farkaslyuk Hungary
<b>Telephone:</b>	+36 48 470758
<b>Email:</b>	<a href="mailto:zoltan.farkas@safegardmedical.hu">zoltan.farkas@safegardmedical.hu</a>
<b>Website address:</b>	<a href="http://www.safegardmedical.com">www.safegardmedical.com</a>
<b>Valid until:</b>	31 May 2026

### Specifications

#### PRODUCT SPECIFICATIONS - MAIN

<b>Intended purpose</b>	Medication variable dose administration	<b>Restrictive use for</b>	Tuberculin administration
<b>Graduations (ml)</b>	0.01	<b>Needle Size</b>	Other
<b>Needle Size (Other)</b>	27G x 1/2"	<b>Needle Fixation</b>	Fixed
<b>Nominal capacity (ml)</b>	1.00	<b>Packaging &amp; Sterility Assurance</b>	Yes
<b>Other needle size options</b>	Yes	<b>Plunger aspiration</b>	Yes
<b>Number of pieces</b>	3.00	<b>RUP mechanism</b>	Needle retraction
<b>RUP Type</b>	Other	<b>Location RUP activation</b>	End of injection
<b>RUP Needle Fixation</b>	Fixed	<b>RUP Needle Sizes</b>	27G x 3/8" (10 mm)
<b>RUP Nominal Capacity (ml)</b>	1.00	<b>RUP plunger Aspiration</b>	Multiple
<b>RUP Primary Packaging</b>	Blister pack	<b>RUP Sub-category</b>	Retractable RUP
<b>CE marking</b>	Yes		
<b>Comments</b>	The retraction of the needle is considered as a reuse prevention feature (RUP) and a Sharp Injury Protection (SIP)		

#### PRICE AND SHIPPING

<b>Shipping volume (m3)</b>	0.056	<b>Shipping weight (kg)</b>	5.40
<b>Pieces per package</b>	100	<b>Minimum order</b>	1000.00
<b>Price 1</b>	0.08 US\$/pc	<b>Year of base price</b>	2016
<b>Incoterms</b>	FCA		

#### QUALITY STANDARD

<b>Quality Standard</b>	ISO 13485	<b>Specification Reference</b>	Applicable PQS specification: ISO 7886-4 Applicable PQS VP(s): ISO 7886-4
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#### PRODUCT SITES

<b>Organization name</b>	Safegard Medical (Hungary) Kft
<b>Address</b>	Jószerecsét tér 15 3608 Farkaslyuk Hungary

<b>Current PQS status:</b>	Prequalified	<b>Valid until:</b>	31 May 2026
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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.