



E013: Injection devices for therapeutic purposes



Product name:	Safegard Retractable Safety syringe 3ml
IMD-PQS Code:	E013-045
Status:	Prequalified
Date of acceptance:	22 Feb 2010
Appliance type:	E013
Product description:	RUP retractable 3ml
Manufacturer:	Safegard Medical (Hungary) Kft
Manufacturers Reference:	Safegard Retractable Safety syringe 3ml
Country of Manufacture:	Hungary
Address:	Jószerecsét tér 15 3608 Farkaslyuk Hungary
Telephone:	+36 48 470758
Email:	zoltan.farkas@safegardmedical.hu
Website address:	www.safegardmedical.com
Valid until:	31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication variable dose administration	Restrictive use for	None
Graduations (ml)	0.10	Needle Size	Other
Needle Size (Other)	23G x 1/2"	Needle Fixation	Fixed
Nominal capacity (ml)	3.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	3.00	RUP mechanism	Needle retraction
RUP Type	Other	Location RUP activation	End of injection
RUP Needle Fixation	Fixed	RUP Needle Sizes	23G x 3/8" (10 mm)
RUP Nominal Capacity (ml)	3.00	RUP plunger Aspiration	Multiple
RUP Primary Packaging	Blister pack	RUP Sub-category	Retractable RUP
CE marking	Yes		

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

PRICE AND SHIPPING

Shipping volume (m3)	0.07	Shipping weight (kg)	7.30
Pieces per package	100	Minimum order	1000.00
Price 1	0.085 US\$/pc	Year of base price	2016
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	Safegard Medical (Hungary) Kft
Address	Jószerecsét tér 15 3608 Farkaslyuk Hungary

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Note: If Current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased.