Version date: 01 Sep 2025



E013

Injection Devices for Therapeutic Uses

The products listed in this new section include single-use Re-use prevention (RUP) syringes for therapeutic use. All prequalified syringes in this category comply with <u>ISO 7886-4 –</u> Sterile hypodermic syringes for single use – Part 4: Syringes with re-use prevention feature.

Guidelines for safe delivery of immunization injection and safe disposal of used syringes and needles can be found in WHO's Immunization in practice: Module 4: Ensuring safe injections.

The performance specification and or verification protocol for this category are currently under development by WHO IMD-PQS for this category. For guidance at the current time, manufacturers and suppliers may refer to to <u>ISO 7886-4 – Sterile hypodermic syringes for single use – Part 4: Syringes with re-use prevention feature.</u>

CATEGORY DOCUMENTATION, GUIDANCE FOR MANUFACTURERS/SUPPLIERS & SUPPORTING INFORMATION FOR USERS

Performance specifications

No WHO IMD-PQS specifications currently available.

<u>ISO 7886-4 – Sterile hypodermic syringes for single use – Part 4: Syringes with re-use prevention feature.</u>

Verification protocols

No WHO IMD-PQS verification protocols currently available.

Guidance for manufacturers/suppliers

Generic guide for the field evaluation of new technologies for WHO PQS prequalification GENERIC/GUIDE 1.1

IMD-PQS Guidelines for Prequalification Holders

Supporting information for users

Guiding principles to ensure injection device security

WHO/PQS/E013 Latest version: September 2024

<u>Immunization in practice: a practical guide for health staff – 2015 update</u>

<u>Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services</u>

WHO/PQS/E013 Latest version: September 2024



E013: Injection devices for therapeutic purposes



Product name: Kojak Selinge 2ml

IMD-PQS Code:E013-001Status:PrequalifiedDate of acceptance:24 Mar 2007

Appliance type: E013

Product description: RUP syringe 2ml

Manufacturer: Hindustan Syringes & Medical Devices Ltd.

Manufacturers Reference: Kojak Selinge 2ml

Country of Manufacture: India

Address: 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Telephone: +91 129-4289000

Email: hmduk@hmdhealthcare.com

Website address: www.hmdhealthcare.com

Valid until: 31 May 2026

Specifications

PRC	וחו	CT	SPF	CIFIC	CATIO	NS -	MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Vaccine capacity (mL) 2.00 Graduations (ml) 0.10

Needle Size Other Needle Size (Other) 23G x 1" (0.60 x 25.4 mm)

Needle FixationFixedNominal capacity (ml)2.00Packaging & SterilityYesOther needle size optionsYes

Assurance

Plunger aspiration Yes Number of pieces 3.00

RUP mechanismLocked/broken plungerRUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes23G x 1" (25 mm)RUP Nominal Capacity (ml)2.00

RUP plunger Aspiration Multiple RUP Primary Packaging Paper or Ribbon pack

RUP Sub-category Simple RUP CE marking Yes

Comments Packs of 100 units

PRICE AND SHIPPING

Shipping volume (m3)0.09Shipping weight (kg)14.50Pieces per package2000Minimum order20000.00

Price 1 USD 3.70/100 Pcs Year of base price 2025

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Hindustan Syringes & Medical Devices Ltd.

Address 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



VanishPoint II® Retractable syringe 3 ml Product name:

IMD-PQS Code: E013-002 Prequalified Status: 15 Jun 2005 Date of acceptance: E013 Appliance type:

Product description: RUP Retractable 3 ml

Manufacturer: Retractable Technologies, Inc.

Manufacturers Reference: VanishPoint II® Retractable syringe 3 ml

Country of Manufacture: United States of America

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 Restrictive use for None

administration

3.00 Vaccine capacity (mL) Graduations (ml) 0.10

Needle Size Other Needle Size (Other) 23G x 1" (25mm)

Needle Fixation Fixed Nominal capacity (ml) 3.00 **Packaging & Sterility** Yes Other needle size options Yes

Assurance

Plunger aspiration Yes Number of pieces 3.00 **RUP** mechanism Retraction of needle into barrel **RUP Type** Other

by spring

Location RUP activation End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 23G x 1" (25 mm) **RUP Nominal Capacity (ml)** 3.00

RUP plunger Aspiration Multiple **RUP Primary Packaging** Paper blister pack

RUP Sub-category Retractable RUP

PRICE AND SHIPPING

Shipping volume (m3) 0.0432 Shipping weight (kg) 5.90 Pieces per package 600 Minimum order 600.00 Price 1 2005 On request Year of base price

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





E013: Injection devices for therapeutic purposes

Product name: VanishPoint II® Retractable 1 ml Tuberculin

IMD-PQS Code:E013-005Status:PrequalifiedDate of acceptance:16 Jun 2005Appliance type:E013

Product description: RUP Retractable 1ml

Manufacturer: Retractable Technologies, Inc.

Manufacturers Reference: VanishPoint II® Retractable 1 ml Tuberculin

Country of Manufacture: United States of America

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

Р	ROD	UCT	SPF	CIFIC/	SNOITA	- MAIN

Intended purpose Medication variable dose Restrictive use for None

administration

Graduations (ml)0.01Needle SizeOtherNeedle Size (Other)27 g x 12.7 mmNeedle FixationFixed

Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism Retraction of needle into barrel

by spring

RUP TypeOtherLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes27G 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)0.0432Shipping weight (kg)4.59Pieces per package800Minimum order800.00Price 1on requestYear of base price2005

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





E013: Injection devices for therapeutic purposes

Product name: VanishPoint II® Retractable 1 ml

IMD-PQS Code:E013-006Status:PrequalifiedDate of acceptance:15 Jun 2005Appliance 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 Restrictive use for None

administration

Vaccine capacity (mL) 1.00 Graduations (ml) 0.01

Needle Size Other Needle Size (Other) 27G x 12.7 mm

Needle FixationFixedNominal capacity (ml)1.00Packaging & SterilityYesOther needle size optionsYes

Assurance

Plunger aspirationYesNumber of pieces3.00RUP mechanismRetraction of needle into barrelRUP TypeOther

by spring

Location RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes27G 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)0.0432Shipping weight (kg)4.50Pieces per package800Minimum order800.00Price 1On requestYear of base price2005

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





E013: Injection devices for therapeutic purposes

Product name: Vanishpoint® Retractable 10ml

IMD-PQS Code:E013-007Status:PrequalifiedDate of acceptance:15 Jun 2005Appliance type:E013

Product description: RUP Retractable 10ml

Manufacturer: Retractable Technologies, Inc.

Manufacturers Reference: Vanishpoint® Retractable 10ml

Country of Manufacture: China

Address: 511 Lobo Lane, Little Elm, TX 75068

Number of pieces

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 Restrictive use for None

administration

Vaccine capacity (mL) 10.00 Graduations (ml) 0.20

Needle Size Other Needle Size (Other) 21Gx1.5" (38mm)

Needle FixationFixedNominal capacity (ml)10.00Packaging & SterilityYesOther needle size optionsYes

Assurance

Plunger aspiration Yes

RUP mechanism Retraction of needle into barrel RUP Type

by spring

Location RUP activation End of injection RUP Needle Fixation

RUP Needle Sizes 21G x 1 1/2" (38 mm) RUP Nominal Capacity (ml) 10.00

The Media Class (III)

RUP plunger Aspiration Multiple RUP Primary Packaging Paper blister pack
RUP Sub-category Retractable RUP

PRICE AND SHIPPING

Shipping volume (m3)0.068Shipping weight (kg)9.70Pieces per package600Minimum order600.00Price 1On requestYear of base price2005

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

3.00

Other

Fixed

PRODUCT SITES

Organization name Retractable Technologies, Inc.

Address 511 Lobo Lane, Little Elm, TX 75068

United States of America

Current PQS status:PrequalifiedValid until:31 May 2026





E013: Injection devices for therapeutic purposes

Product name: VanishPoint II® Retractable 5ml

IMD-PQS Code: F013-008 Prequalified Status: 16 Jun 2005 Date of acceptance: Appliance type: E013

Product description: **RUP Retractable 5ml**

Manufacturer: Retractable Technologies, Inc. Manufacturers Reference: VanishPoint II® Retractable 5ml

Country of Manufacture:

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 Restrictive use for None

administration

5.00 Vaccine capacity (mL) Graduations (ml) 0.20

Needle Size Other Needle Size (Other) 21Gx1.5" (38mm)

Needle Fixation Fixed Nominal capacity (ml) 5.00 **Packaging & Sterility** Yes Other needle size options Yes

Assurance

Plunger aspiration Yes Number of pieces 3.00 **RUP** mechanism Retraction of needle into barrel **RUP Type** Other

by spring

Location RUP activation End of injection **RUP Needle Fixation** 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 Retractable RUP

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

Protection (SIP)

PRICE AND SHIPPING

0.045 Shipping weight (kg) 8.20 Shipping volume (m3) Pieces per package 600 Minimum order 600.00 Price 1 Year of base price 2005 On request

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: Valid until: Prequalified 31 May 2026





E013: Injection devices for therapeutic purposes



Product name: Vanishpoint® Retractable 3ml

IMD-PQS Code: E013-009 Prequalified Status: 16 Jun 2005 Date of acceptance: Appliance type: E013

Product description: RUP retractable 3ml

Manufacturer: Retractable Technologies, Inc. Manufacturers Reference: Vanishpoint® Retractable 3ml

Country of Manufacture:

Address: 511 Lobo Lane, Little Elm, TX 75068

United States of America

www.retractable.com

Telephone: +1 972 294 1010

Email: kduesman@retractable.com

Valid until: 31 May 2026

Specifications

Assurance

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None

Website address:

administration

3.00 Vaccine capacity (mL) Graduations (ml) 0.10

Needle Size Other Needle Size (Other) 23Gx1" (25mm)

Needle Fixation Fixed Nominal capacity (ml) 3.00 **Packaging & Sterility** Yes Other needle size options Yes

Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism **RUP Type** Other Needle retraction into barrel by

spring

Location RUP activation End of injection **RUP Needle Fixation** Fixed

RUP Needle Sizes 23G x 1" (25 mm) **RUP Nominal Capacity (ml)** 3.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Paper blister pack

RUP Sub-category Retractable RUP

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

Protection (SIP)

PRICE AND SHIPPING

0.0432 Shipping weight (kg) 5.90 Shipping volume (m3) Pieces per package 600 Minimum order 600.00 Price 1 Year of base price 2005 On request

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: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: VanishPoint II® Retractable 1 ml Insulin

IMD-PQS Code:E013-014Status:PrequalifiedDate of acceptance:15 Jun 2005Appliance type:E013

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

Manufacturers Reference: VanishPoint II® Retractable 1 ml Insulin

Country of Manufacture: United States of America

Address: 511 Lobo Lane, Little Elm, TX 75068

United States of America

www.retractable.com

Telephone: +1 972 294 1010

Email: kduesman@retractable.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication fixed dose Restrictive use for Insulin administration

administration

Vaccine capacity (mL)1.00Needle SizeOtherNeedle Size (Other)29G x 12.7 mmNeedle FixationFixed

Website address:

Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism Retraction of needle into barrel

by spring

RUP TypeOtherLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes29G 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)0.0432Shipping weight (kg)4.50Pieces per package800Minimum order800.00Price 1On requestYear of base price2005

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



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

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 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



E013: Injection devices for therapeutic purposes



Product name: Kojak Selinge 5ml

IMD-PQS Code:E013-018Status:PrequalifiedDate of acceptance:24 Feb 2008

Appliance type: E013

Product description: RUP syringe 5ml

Manufacturer: Hindustan Syringes & Medical Devices Ltd.

Manufacturers Reference: Kojak Selinge 5ml

Country of Manufacture: India

Address: 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Telephone: +91 129-4289000

Email: hmduk@hmdhealthcare.com

Website address: www.hmdhealthcare.com

Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATIONS -	MAIN

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Vaccine capacity (mL) 5.00 Graduations (ml) 0.20

Needle Size Other Needle Size (Other) 21G x 1 1/2" (0.80 x 38 mm)

Needle FixationFixedNominal capacity (ml)5.00Packaging & SterilityYesOther needle size optionsYes

Assurance

Plunger aspiration Yes Number of pieces 3.00

RUP mechanismlocked/broken plungerRUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes21G x 1 1/2" (38 mm)RUP Nominal Capacity (ml)5.00

RUP plunger Aspiration Multiple RUP Primary Packaging Paper or Ribbon pack

RUP Sub-category Simple RUP CE marking Yes

Comments Packs of 100 units

PRICE AND SHIPPING

 Shipping volume (m3)
 0.08
 Shipping weight (kg)
 12.60

 Pieces per package
 200
 Minimum order
 2000.00

 Price 1
 USD 4.05/100 Pcs
 Year of base price
 2025

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Hindustan Syringes & Medical Devices Ltd.

Address 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product description: RUP syringe 3ml

Manufacturer: PT Oneject Indonesia

Manufacturers Reference: Oneject K1 3ml

Country of Manufacture: Indonesia

Address: Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor

16810, Indonesia Indonesia

Telephone: +62 21 879 17 422

Email: niken.permatasari@oneject.co.id

Website address: www.oneject.co.id
Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)23G x 1 1/4"Needle FixationFixedNominal capacity (ml)3.00Packaging & SterilityYes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism Locked & broken plunger

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes23G x 1" (25 mm)

RUP Nominal Capacity (ml)3.00RUP plunger AspirationMultipleRUP Primary PackagingBlister packRUP Sub-categorySimple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3)0.11Shipping weight (kg)13.60Pieces per package1800Minimum order18000.00Price 1On request to manufacturerYear of base price2010

Incoterms FOB

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS VP(s): ISO 7886-4

PRODUCT SITES

Organization name PT Oneject Indonesia

Address Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status:PrequalifiedValid until:31 May 2026



E013: Injection devices for therapeutic purposes



Kojak Selinge 10 ml



E013-020 Prequalified

Status:

Date of acceptance:

03 Aug 2007

Appliance type:

E013

Product description:

RUP syringe 10ml

Manufacturer:

Hindustan Syringes & Medical Devices Ltd.

Manufacturers Reference:

Kojak Selinge 10 ml

Country of Manufacture:

Address:

174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Telephone:

+91 129-4289000

Email: Website address: hmduk@hmdhealthcare.com www.hmdhealthcare.com

Valid until:

31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose

Medication variable dose

None

administration; Medication variable dose reconstitution

Graduations (ml)

Vaccine capacity (mL)

10.00 Other

Restrictive use for

21G x 1 1/2" (0.80 x 38mm)

Needle Fixation

Detached

Needle Size (Other) Nominal capacity (ml)

10.00

Packaging & Sterility

Yes

Other needle size options

Yes

Assurance

Needle Size

Yes

Number of pieces

3.00

Plunger aspiration **RUP** mechanism

Locked/broken plunger

RUP Type

Plunger lock

Location RUP activation

End of injection

RUP Needle Fixation

RUP Needle Sizes

21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml)

Not Fixed

RUP plunger Aspiration

RUP Primary Packaging

10.00

RUP Sub-category

Multiple Simple RUP

CE marking

Paper or Ribbon pack

Comments

Packs of 50 units or 100 units

PRICE AND SHIPPING

Shipping volume (m3)

0.09

Shipping weight (kg)

13.40

Pieces per package

900

FCA

Minimum order

9000.00

Price 1 Incoterms USD 4,80/100 Pcs

Year of base price

2025

Yes

QUALITY STANDARD

Quality Standard

ISO 13485;Other

Quality standard (Other)

ISO 9001

Specification Reference

Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name

Hindustan Syringes & Medical Devices Ltd.

Address

174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Current PQS status:

Prequalified

Valid until:

31 May 2026



E013: Injection devices for therapeutic purposes

Oneject K1 1ml Product name: IMD-PQS Code: E013-023 Prequalified Status: 05 Jul 2007 Date of acceptance: E013 Appliance type:

Product description: RUP syringe 1ml Manufacturer: PT Oneject Indonesia Manufacturers Reference: Oneject K1 1ml Country of Manufacture: Indonesia

Address: Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor

16810, Indonesia Indonesia

Telephone: +62 21 879 17 422

Email: niken.permatasari@oneject.co.id

Website address: www.oneject.co.id Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication fixed dose Restrictive use for Fixed dose 1ml

administration; Medication fixed

dose reconstitution

Graduations (ml) 1.00 **Needle Size** Other 23G x 1" **Needle Fixation** Fixed Needle Size (Other) Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Locked & broken plunger

RUP Type Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 1.00 **RUP plunger Aspiration** Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 13.60 0.11 Shipping weight (kg) Pieces per package 1800 Minimum order 18000.00 Price 1 On request to manufacturer Year of base price 2010

Incoterms FOB

QUALITY STANDARD

Quality Standard Quality standard (Other) ISO 9001 ISO 13485;Other

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name PT Oneject Indonesia

Address Sentul Industrial Estate Jl. Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Oneject K1 5ml Product name: IMD-PQS Code: E013-024 Prequalified Status: Date of acceptance: 21 May 2007 E013 Appliance type:

Product description: RUP syringe 5ml Manufacturer: PT Oneject Indonesia Manufacturers Reference: Oneject K1 5ml Country of Manufacture: Indonesia

Address: Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor

Yes

16810, Indonesia Indonesia

Telephone: +62 21 879 17 422

Email: niken.permatasari@oneject.co.id

Website address: www.oneject.co.id Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.20 **Needle Size** Other 21G x 1 1/2" **Needle Fixation** Detached Needle Size (Other)

Nominal capacity (ml) 5.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger locked and broken

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** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.09 11.10 Shipping weight (kg) Pieces per package 1200 Minimum order 12000.00 Price 1 On request to manufacturer Year of base price 2008

Incoterms FOB

QUALITY STANDARD

Quality Standard Quality standard (Other) ISO 9001 ISO 13485;Other

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name PT Oneject Indonesia

Address Sentul Industrial Estate Jl. Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Yushou 3ml Product name: IMD-PQS Code: E013-029 Status: Prequalified Date of acceptance: 27 May 2008

E013 Appliance type:

Product description: RUP syringe 3ml

Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: Yushou 3ml Country of Manufacture:

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China China

Telephone: +86 (510)3777555 Email: mike@chinasyringe.com Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PR	ODL	JCT	SPE	CIFIC	ATIONS	- MAIN
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Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.10 **Needle Size** Other Needle Size (Other) **Needle Fixation** Detached 23G x 1 1/4"

Nominal capacity (ml) 3.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger lock with clip **RUP Type** Plunger lock **Location RUP activation** Start of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 3.00 **RUP plunger Aspiration** Single Simple RUP

RUP Primary Packaging Blister pack **RUP Sub-category**

CE marking Yes

PRICE AND SHIPPING

13.00 2400 Shipping weight (kg) Pieces per package

200000.00 Price 1 Minimum order On request to manufacturer

Year of base price 2021 Incoterms **FOB**

QUALITY STANDARD

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

Yes

PRODUCT SITES

Organization name Wuxi Yushou Medical Appliances Co., Ltd

Address No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu Province China

China

Current PQS status: Valid until: 31 May 2026 Prequalified



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-034 Prequalified Status: Date of acceptance: 30 Apr 2009

Appliance type: E013

Product description:

RUP syringe 2ml Guangdong Haiou Medical Apparatus Co., Ltd Manufacturer:

Haiou syringe 2ml Manufacturers Reference:

Country of Manufacture:

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

+86-663-2758666 Telephone: Email: market01@haiou.net.cn Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

PI	R	0	DI	U	CT	SF	E	CII	FIC	AT	ΊO	NS	-	MAIN
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Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.10 **Needle Size** Other Needle Size (Other) **Needle Fixation** Detached 23G x 25mm

Nominal capacity (ml) 2.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger break **RUP Type** Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 2.00 **RUP plunger Aspiration** Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 15.50 0.118 Shipping weight (kg) Pieces per package 2400 Minimum order 100000.00 Price 1 On request Year of base price 2008

Incoterms FOB

QUALITY STANDARD

Quality Standard ISO 13485 Applicable PQS specification: Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

Yes

PRODUCT SITES

Guangdong Haiou Medical Apparatus Co., Ltd Organization name

Address Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China

China

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-035 Prequalified Status: Date of acceptance: 30 Apr 2009

Appliance type: E013

Product description: RUP syringe 5ml Guangdong Haiou Medical Apparatus Co., Ltd Manufacturer:

Haiou syringe 5ml Manufacturers Reference:

Country of Manufacture:

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

+86-663-2758666 Telephone: Email: market01@haiou.net.cn Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

PI	R	0	DI	U	CT	SF	E	CII	FIC	AT	ΊO	NS	-	MAIN
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Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.20 **Needle Size** Other Needle Size (Other) **Needle Fixation** Detached 21G x 40mm

Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger 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 Blister pack **RUP Sub-category** Simple RUP

CE marking

Yes

PRICE AND SHIPPING

Shipping volume (m3) 16.00 0.116 Shipping weight (kg) Pieces per package 1800 Minimum order 100000.00 Price 1 On request Year of base price 2008

Incoterms FOB

QUALITY STANDARD

Quality Standard ISO 13485 Applicable PQS specification: Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Guangdong Haiou Medical Apparatus Co., Ltd Organization name

Address Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China

China

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code:E013-036Status:PrequalifiedDate of acceptance:30 Apr 2009

Appliance type: E013

Product description: RUP syringe 10ml

Manufacturer: Guangdong Haiou Medical Apparatus Co., Ltd

Manufacturers Reference: Haiou syringe 10ml

Country of Manufacture: China

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

China

Telephone: +86-663-2758666

Email: market01@haiou.net.cn

Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml)1.00Needle SizeOtherNeedle Size (Other)21G x 40mmNeedle FixationDetached

Nominal capacity (ml) 10.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

 Number of pieces
 3.00
 RUP mechanism
 Plunger break

 RUP Type
 Plunger lock
 Location RUP activation
 End of injection

 PUR Needle Fixetion
 Not Fixed
 PUR Needle Sizes
 21G x 1 1/2" (38 mm)

RUP Needle FixationNot FixedRUP Needle Sizes21G x 1 1/2" (38 mm)RUP Nominal Capacity (ml)10.00RUP plunger AspirationMultiple

RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

PRICE AND SHIPPING

CE marking

Shipping volume (m3)0.11Shipping weight (kg)15.50Pieces per package1200Minimum order100000.00Price 1On requestYear of base price2008

Incoterms FOB

QUALITY STANDARD

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

Yes

PRODUCT SITES

Organization name Guangdong Haiou Medical Apparatus Co., Ltd

Address Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China

China

Yes

Current PQS status:PrequalifiedValid until:31 May 2026





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-037Status:SuspendedDate of acceptance:21 May 2009Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-038Status:SuspendedDate of acceptance:21 May 2009Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:



E013: Injection devices for therapeutic purposes



Product name: Kojak Selinge 20ml

IMD-PQS Code: E013-039 Prequalified Status: 18 Jun 2009 Date of acceptance: Appliance type: E013

Product description: RUP syringe 20ml

Manufacturer: Hindustan Syringes & Medical Devices Ltd.

Manufacturers Reference: Kojak Selinge 20ml

Country of Manufacture:

Address: 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Telephone: +91 129-4289000

Email: hmduk@hmdhealthcare.com Website address: www.hmdhealthcare.com

Valid until: 31 May 2026

Specifications

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Intended purpose Medication variable dose Restrictive use for None

> administration; Medication variable dose reconstitution

Vaccine capacity (mL) 20.00 Graduations (ml)

Other Needle Size (Other) **Needle Size** 21G x 1 1/2" (0.80 x 38 mm)

Needle Fixation Detached Nominal capacity (ml) 20.00 Packaging & Sterility Yes Other needle size options Yes

Assurance

Plunger aspiration Yes Number of pieces 3.00

RUP mechanism locked/broken plunger **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)** 20.00

RUP plunger Aspiration Multiple **RUP Primary Packaging** Paper or Ribbon pack

RUP Sub-category Simple RUP **CE** marking Yes

Comments Packs of 25 units

PRICE AND SHIPPING

Shipping volume (m3) 0.103 Shipping weight (kg) 13.00 Pieces per package 400 Minimum order 4000.00 Price 1 2025 USD 9.50/100 Pcs

Year of base price

Incoterms **FCA**

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Hindustan Syringes & Medical Devices Ltd. Organization name

Address 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: Revital 5ml (3 piece)

IMD-PQS Code: E013-040 Prequalified Status: 09 Feb 2009 Date of acceptance:

Appliance type: E013

Product description: RUP syringe 5ml

Manufacturer: Revital Health Care (EPZ) Limited

Manufacturers Reference: Revital 5ml (3 piece)

Country of Manufacture:

Address: P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239,

Takaungu 80100 Mombasa Kenya

Telephone: +254722412900 Email: ga@rhcare-epz.com Website address: www.revitalhcare.com

Valid until: 31 May 2026

Specifications

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.20 **Needle Size** Other

Needle Size (Other) **Needle Fixation** Detached 21Gx1 1/2" (38mm) Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Plunger aspiration

Other needle size options Yes Yes **Number of pieces** 3.00 **RUP** mechanism

Plunger (gasket) lock **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

Plunger gasket can be provided in black or whit Comments

PRICE AND SHIPPING

0.141 Shipping weight (kg) 21.50 Shipping volume (m3) Pieces per package 2500 Minimum order 500000.00 Price 1 0.05 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

Kenya

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: Yushou Syringe 1ml

IMD-PQS Code:E013-041Status:PrequalifiedDate of acceptance:15 Sep 2009

Appliance type: E013

Product description: RUP syringe 1ml

Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: Yushou Syringe 1ml

Country of Manufacture: China

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China

China

Telephone: +86 (510)3777555
Email: mike@chinasyringe.com

Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None
Vaccine capacity (mL)	1.00	Graduations (ml)	0.05
Needle Size	Other	Needle Size (Other)	25G x 20mm
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	Plunger lock with metallic clip	RUP Type	Plunger lock

Location RUP activationStart of injectionRUP Needle FixationFixedRUP Needle Sizes25G x 3/4" (20 mm)RUP Nominal Capacity (ml)1.00

RUP plunger Aspiration Single RUP Primary Packaging Paper blister pack

RUP Sub-category Simple RUP CE marking Yes

Comments Plunger aspiration: Single

PRICE AND SHIPPING

Shipping volume (m3)0.094Shipping weight (kg)11.00Pieces per package2400Minimum order200000.00Price 1On requestYear of base price2008IncotermsFCA

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

QUALITY STANDARD

Organization name Wuxi Yushou Medical Appliances Co., Ltd

Address No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu Province China

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-042 Prequalified Status: Date of acceptance: 01 Aug 2009

E013 Appliance type:

Product description: 2ml 3 piece RUP syringe

Manufacturer: Revital Health Care (EPZ) Limited

Manufacturers Reference: Revital 2ml (3 piece)

Country of Manufacture:

Address: P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239,

Takaungu 80100 Mombasa Kenya

Telephone: +254722412900 Email: ga@rhcare-epz.com Website address: www.revitalhcare.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.10 **Needle Size** Other **Needle Fixation** Detached Needle Size (Other) 23G x 1"

Nominal capacity (ml) 2.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger block and break

RUP Type Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 2.00 **RUP plunger Aspiration** Multiple **RUP Primary Packaging** Paper blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 19.50 0.13 Shipping weight (kg) Pieces per package 3500 Minimum order 700000.00 Price 1 Per unit: 0.027 US\$ Year of base price 2008

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485 Applicable PQS specification: Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

Yes

PRODUCT SITES

Revital Health Care (EPZ) Limited Organization name

Address P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239, Takaungu 80100 Mombasa Kenya

Kenya

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



Revital 5ml (2 piece) Product name:

IMD-PQS Code: E013-043 Prequalified Status: Date of acceptance: 01 Aug 2009

E013 Appliance type:

Product description: RUP syringe 5ml

Manufacturer: Revital Health Care (EPZ) Limited

Manufacturers Reference: Revital 5ml (2 piece)

Country of Manufacture:

Address: P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239,

Takaungu 80100 Mombasa Kenya

Telephone: +254722412900 Email: ga@rhcare-epz.com Website address: www.revitalhcare.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.20 **Needle Size** Other

Needle Fixation Detached Needle Size (Other) 21Gx1 1/2" (38mm) Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Plunger aspiration

Other needle size options Yes 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) 17.60 0.128 Shipping weight (kg) 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

Revital Health Care (EPZ) Limited Organization name

Address P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239, Takaungu 80100 Mombasa Kenya

Kenya

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code:E013-044Status:PrequalifiedDate of acceptance:22 Feb 2010

Appliance type: E013

Product description:RUP retractable 1ml TuberculinManufacturer:Safegard Medical (Hungary) Kft

Manufacturers Reference: Safegard Retractable safety syringe 1ml Tuberculin

Country of Manufacture: Hungary

Address: Jószerencsét 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 Restrictive use for Tuberculin administration

administration

Graduations (ml)0.01Needle SizeOtherNeedle Size (Other)27G x 1/2"Needle FixationFixedNominal capacity (ml)1.00Packaging & SterilityYes

Assurance

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
 27G x 3/8" (10 mm)

RUP Nominal Capacity (ml) 1.00 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)
 0.056
 Shipping weight (kg)
 5.40

 Pieces per package
 100
 Minimum order
 1000.00

 Price 1
 0.08 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 Jószerencsét tér 15 3608 Farkaslyuk

Hungary

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: Safegard Retractable Safety syringe 3ml

IMD-PQS Code: E013-045 Status: Prequalified 22 Feb 2010 Date of acceptance:

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: Jószerencsét 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 Protection (SIP)	considered as a reuse prevention	feature (RUP) and a Sharp Injury
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 Jószerencsét tér 15 3608 Farkaslyuk

Hungary

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: Safegard Retractable Safety Syringe 5ml

IMD-PQS Code:E013-046Status:PrequalifiedDate of acceptance:22 Feb 2010

Appliance type: E013

Product description: RUP retractable 5ml

Manufacturer: Safegard Medical (Hungary) Kft

Manufacturers Reference: Safegard Retractable Safety Syringe 5ml

Country of Manufacture: Hungary

Address: Jószerencsét 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

Address

Current PQS status:

tration;Medication	Restrictive use for	None
ı	Needle Size	Other
1/4"	Needle Fixation	Fixed
		Yes
F	Plunger aspiration	Yes
F	RUP mechanism	Needle retraction into barrel
l	Location RUP activation	End of injection
F	RUP Needle Sizes	21G x 1 1/4" (30 mm)
F	RUP plunger Aspiration	Multiple
oack F	RUP Sub-category	Retractable RUP
action of the needle is conson (SIP)	sidered as a reuse prevention	n feature (RUP) and a Sharp Injury
o (o)		
o (o)		
· , ,	Shipping weight (kg)	9.68
	Shipping weight (kg) Minimum order	9.68 1000.00
\$		
\$	Minimum order	1000.00
\$	Minimum order	1000.00
\$\$/pc	Minimum order	1000.00 2016
\$\$/pc	Minimum order Year of base price	1000.00 2016 Applicable PQS specification: ISO 7886-4 Applicable PQS
	etration;Medication e dose reconstitution 1/4" 1 pack raction of the needle is con	tration; Medication e dose reconstitution Needle Size 1/4" Needle Fixation Packaging & Sterility Assurance Plunger aspiration RUP mechanism Location RUP activation RUP Needle Sizes RUP plunger Aspiration Pack RUP Sub-category

Valid until:

31 May 2026

Jószerencsét tér 15 3608 Farkaslyuk

Hungary

Prequalified



E013: Injection devices for therapeutic purposes



IMD-PQS Code:E013-051Status:PrequalifiedDate of acceptance:26 Apr 2010

Appliance type: E013

Product description: RUP syringe 2ml

Manufacturer: Revital Health Care (EPZ) Limited

Manufacturers Reference: Revital 2ml (2 piece)

Country of Manufacture: Kenya

Address: P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239,

Takaungu 80100 Mombasa Kenya

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 Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)23G x 1"Needle FixationDetached

Nominal capacity (ml) 2.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces2.00RUP mechanismPlunger lock and break

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes23G x 1" (25 mm)

RUP Nominal Capacity (ml) 2.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Paper blister pack RUP Sub-category Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.13 Shipping weight (kg) 17.50

Pieces per package 3500 Minimum order 700000.00

Price 1 Up to 5 millions: 0.028 US\$ Price 2 Up to 10 millions: 0.0275 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

Yes

PRODUCT SITES

Organization name Revital Health Care (EPZ) Limited

Address P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239, Takaungu 80100 Mombasa Kenya

Kenya

Current PQS status:PrequalifiedValid until:31 May 2026



E013: Injection devices for therapeutic purposes



Product name: Hongda syringe 2ml SD02L

IMD-PQS Code:E013-053Status:PrequalifiedDate of acceptance:06 Sep 2010

Appliance type: E013

Product description: RUP syringe 2ml

Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd

Manufacturers Reference: Hongda syringe 2ml SD02L

Country of Manufacture: China

Address: 39 South Shengi Road Jinxian county, Nanchang City

Jiangxi province China; People's Republic of

China

Telephone: +86 791 85628828
Email: hongda008@jxhd.cn
Website address: http://www.jxhd.cn
Valid until: 31 May 2026

Specifications

PR	ODU	CT	SPE	CIFIC	ATIONS	- MAIN
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 Intended purpose
 Medication variable dose administration; Medication
 Restrictive use for administration; Medication
 None

variable dose reconstitution

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)21G x 38mmNeedle FixationDetached

Nominal capacity (ml) 2.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism gasket lock/ plunger break

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 2.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

CE marking Yes

Comments Option 2000 or 2400 per cartons Needle at side available Fixed needle option available

Graduations: with scale interval of 0.1ml and 0.5ml increment between graduation lines to be

numbered.

PRICE AND SHIPPING

Shipping volume (m3)0.106Shipping weight (kg)17.00Pieces per package2500Minimum order525000.00Price 1On requestYear of base price2016

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 Jiangxi Hongda Medical Equipment Group Ltd

Address 39 South Shengi Road Jinxian county, Nanchang City Jiangxi province China; People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: Hongda syringe 5ml SD05L

IMD-PQS Code:E013-054Status:PrequalifiedDate of acceptance:06 Sep 2010

Appliance type: E013

Product description: RUP syringe 5ml

Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd

Manufacturers Reference: Hongda syringe 5ml SD05L

Country of Manufacture: China

Address: 39 South Shengi Road Jinxian county, Nanchang City

Jiangxi province China; People's Republic of

China

Telephone: +86 791 85628828
Email: hongda008@jxhd.cn
Website address: http://www.jxhd.cn
Valid until: 31 May 2026

Specifications

PF	30	DUCT	SPE	CIFIC	ATIONS	- MAIN
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Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml)0.20Needle SizeOtherNeedle Size (Other)21G x 38mmNeedle FixationDetached

Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism gasket lock/ plunger break

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 5.00 RUP plunger Aspiration Multiple
RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

CE marking Yes

Other needle size options

Comments Option of 2000 pieces per carton Fixed needles are also an option Needle at side available Pieces

per carton: 2000 or 1800 Graduations: with scale interval of 0.2ml and 1ml increment between

graduation lines to be numbered.

PRICE AND SHIPPING

Shipping volume (m3)0.124Shipping weight (kg)19.00Pieces per package1500Minimum order525000.00Price 1On requestYear of base price2009

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 Jiangxi Hongda Medical Equipment Group Ltd

Address 39 South Shengi Road Jinxian county, Nanchang City Jiangxi province China; People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Nisa RUP syringe 5ml

IMD-PQS Code: Status:

Product name:

Prequalified

E013-055

Date of acceptance:

30 Aug 2010

Appliance type:

E013

Product description:

RUP syringe 5ml

Manufacturer:

Chengdu Xinjin Shifeng Medical Apparatus & Instrument

Co., Ltd.

Manufacturers Reference:

Nisa RUP syringe 5ml

Country of Manufacture:

China

Address:

NO. 51, 4th Group Wanjie Village, Baodun Town, Xinjin District

Chengdu Sichuan China

Telephone: Email: +86 2885157183 sfyx_1998@163.com

Website address: www.xjshifeng,com Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose

Medication variable dose administration; Medication

Restrictive use for

None

Graduations (ml)
Needle Size (Other)

0.20 23G x 1"

variable dose reconstitution

Needle Fixation

Other Detached

Nominal capacity (ml)

Other needle size options

5.00

3.00

Yes

Packaging & Sterility Assurance

Needle Size

Yes

Yes

Plunger aspiration RUP mechanism

Locked broken plunger

Number of pieces

RUP Type

CE marking

Plunger lock

Location RUP activation

End of injection 23G x 1" (25 mm)

RUP Needle Fixation
RUP Nominal Capacity (ml)

Not Fixed 5.00 RUP Needle Sizes
RUP plunger Aspiration

Multiple

RUP Primary Packaging

Blister pack

RUP Sub-category

Simple RUP

PRICE AND SHIPPING

Shipping volume (m3) Pieces per package

0.122 1600 0.055 USD Shipping weight (kg) Minimum order Year of base price 17.00 1600.00

2009

Price 1 Incoterms

FCA

QUALITY STANDARD

ISO 13485:Other

Quality standard (Other)

ISO 9001

Specification Reference

Applicable PQS specification: ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Quality Standard

Organization name

Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd.

Address

NO. 51, 4th Group Wanjie Village, Baodun Town, Xinjin District Chengdu Sichuan

China

Valid until: **Current PQS status:** Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



Kojak Selinge 1 ml Product name:

IMD-PQS Code: E013-056 Prequalified Status: Date of acceptance: 16 Sep 2010

Appliance type: E013

Product description: RUP 1ml fixed dose

Manufacturer: Hindustan Syringes & Medical Devices Ltd.

Kojak Selinge 1 ml Manufacturers Reference:

Country of Manufacture:

Address: 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Telephone: +91 129-4289000

Email: hmduk@hmdhealthcare.com Website address: www.hmdhealthcare.com

Valid until: 31 May 2026

Specifications

Intended purpose	Medication fixed dose
	administration;Medicati

PRODUCT SPECIFICATIONS - MAIN

Restrictive use for Fixed dose 1ml

nistration; Medication fixed dose reconstitution

Yes

Yes

0.09

2000

FCA

Vaccine capacity (mL) 1.00 **Needle Size** Other **Needle Fixation** Fixed

Needle Size (Other) 24G x 25mm Nominal capacity (ml) 1.00

Packaging & Sterility

Other needle size options Yes

Graduations (ml)

Assurance

Number of pieces

Plunger aspiration **RUP** mechanism

Locked/broken plunger **RUP Type** Plunger lock

1.00

3.00

Fixed

Yes

Location RUP activation RUP Needle Sizes

End of injection 24G x 1" (25 mm)

RUP Nominal Capacity (ml)

1.00

RUP plunger Aspiration **RUP Sub-category**

Multiple Simple RUP **RUP Primary Packaging CE** marking

RUP Needle Fixation

Paper or Ribbon pack

Comments Packs of 100 units

PRICE AND SHIPPING

Shipping volume (m3) Pieces per package

Shipping weight (kg) Minimum order

13.70 20000.00

Price 1 USD 3.75/100 Pcs

Year of base price

2025

QUALITY STANDARD

Incoterms

Quality Standard Specification Reference ISO 13485;Other

Quality standard (Other)

ISO 9001

PRODUCT SITES

Organization name

Hindustan Syringes & Medical Devices Ltd.

Address

174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

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.

Applicable PQS specification: Applicable PQS VP(s):



E013: Injection devices for therapeutic purposes



Appliance type:

Product description: **RUP 1ml Sanxin**

Manufacturer: Jiangxi Sanxin Medtec Co., Ltd

Manufacturers Reference: YIXIN 1 ml Country of Manufacture:

Address: 999 Fushan Road, Xiaolan Economic Development Zone,

Nanchang, Jiangxi, P.C. 330200 China; People's Republic

Other

of China

Needle Size

Telephone: +86 791 85988111 Email: fgb@sanxin-med.com Website address: www.sanxin-med.com

Valid until: 31 May 2026

Specifications

PRODUCT 1	SPECIFICAT	IONS - MAIN
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Medication fixed dose Restrictive use for Fixed dose 1ml Intended purpose administration; Medication fixed

dose reconstitution

Graduations (ml) 1.00

Needle Size (Other) 25G x 19 mm **Needle Fixation** Fixed Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger locked **Location RUP activation RUP Type** Plunger lock End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 25G x 2/3" (17 mm)

RUP Nominal Capacity (ml) 1.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.12 Shipping weight (kg) 15.00 3000 Pieces per package Minimum order 200000.00 Price 1 0.0395 USD Year of base price 2012

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 Jiangxi Sanxin Medtec Co.,Ltd

Address 999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, P.C. 330200 China;

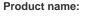
People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Yushou® RUP 5ml

IMD-PQS Code:

E013-058

Status:

Prequalified

Date of acceptance:

03 Jul 2011

Appliance type:

E013

Product description:

RUP syringe 5ml

Manufacturer:

Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference:

Yushou® RUP 5ml

Address:

variable dose reconstitution

No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China

China

Telephone: +86 (510)3777555 Email: mike@chinasyringe.com Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose administration; Medication Restrictive use for

None

Graduations (ml)

Needle Size (Other) 21G x 1 1/2'

Needle Fixation

Other Fixed

5.00 Nominal capacity (ml)

Packaging & Sterility **Assurance**

Needle Size

Yes

Other needle size options

Yes

Plunger aspiration **RUP** mechanism

Yes Locked / broken plunger

Number of pieces

3.00 Plunger lock

Location RUP activation

End of injection

RUP Type RUP Needle Fixation

Fixed

RUP Needle Sizes

21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml)

5.00

RUP plunger Aspiration

Multiple

RUP Primary Packaging

Blister pack

RUP Sub-category

Simple RUP

CE marking

Yes

PRICE AND SHIPPING

Shipping volume (m3)

QUALITY STANDARD

0.103

Shipping weight (kg)

13.00

Pieces per package

1800

Minimum order Year of base price

200000.00 2021

Price 1 Incoterms

FCA

Quality Standard ISO 13485 **Specification Reference**

Applicable PQS specification: Applicable PQS VP(s):

PRODUCT SITES

Organization name

Wuxi Yushou Medical Appliances Co., Ltd

Address

No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu Province China

China

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.

Upon request to manufacturer



E013: Injection devices for therapeutic purposes



Revital® RUP 10ml 2 piece syringe Product name:

IMD-PQS Code: E013-062 Status: Prequalified Date of acceptance: 05 Sep 2011 E013 Appliance type:

Product description: RUP 10ml (2 piece)

Manufacturer: Revital Health Care (EPZ) Limited Manufacturers Reference: Revital® RUP 10ml 2 piece syringe

Address: P.O. BOX 80713-80100 MOMBASA LR No. 5025/1239,

Takaungu 80100 Mombasa Kenya

Kenya

Telephone: +254722412900 Email: qa@rhcare-epz.com Website address: www.revitalhcare.com

Valid until: 31 May 2026

Specifications

PRODUCT 1	SPECIFICAT	IONS - MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 21G x 1.5" **Needle Fixation** Detached

PPE, Polyethylene Syringe material(s) Other Syringe Material(s) (Other)

Nominal capacity (ml) 10.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 2.00 **RUP** mechanism locked, broken plunger **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)** 10.00 **RUP plunger Aspiration** Multiple

RUP Primary Packaging Plastic ribbon **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 19.80 0.1874 Shipping weight (kg) Pieces per package 2500 Minimum order 500000.00

Price 1 Over 1 million: 6.80 USD per Price 2 Over 5 millions: 6.60 USD per pack

pack

Yes

Price 3 Over 10 millions: 6.50 USD per Year of base price 2011

pack

Incoterms **EXW**

QUALITY STANDARD

Applicable PQS specification: **Quality Standard** ISO 13485 **Specification Reference**

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

Kenya

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Sanzhong® 1ml Product name: IMD-PQS Code: E013-064 Prequalified Status: Date of acceptance: 14 Sep 2011

Appliance type: E013

Product description: RUP syringe 1ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: Sanzhong® 1ml

Country of Manufacture:

Address: No. 228, Weiyi Road Economic Development Zone 239300

> Tianchang China

+86 550 7308592 Telephone: Email: marshall988@163.net Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.05 **Needle Size** Other Needle Size (Other) 27G x 1/2" **Needle Fixation** Detached

Nominal capacity (ml) 1.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger locked at end of

injection

2011

Yes

Location RUP activation RUP Type Plunger lock End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 27G x 3/8" (10 mm)

1.00 **RUP Nominal Capacity (ml) RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.072 Shipping weight (kg) 10.00 2000 Minimum order 200000.00 Pieces per package

Price 1 Over 200 000 units: 0.0407 USD Price 2 Over 1 000 000 units: 0.0399

> USD per unit Year of base price

Over 5 000 000 units: 0.0387

USD per unit

per unit

Incoterms **FOB**

Quality Standard ISO 13485 Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

QUALITY STANDARD

Price 3

Organization name Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Sanzhong® 2ml Product name: IMD-PQS Code: E013-065 Prequalified Status: Date of acceptance: 14 Sep 2011

E013 Appliance type:

Product description: RUP syringe 2ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: Sanzhong® 2ml

Country of Manufacture:

Address: No. 228, Weiyi Road Economic Development Zone 239300

> Tianchang China

+86 550 7308592 Telephone: Email: marshall988@163.net Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.10 **Needle Size** Other **Needle Fixation** Detached Needle Size (Other) 23G x 1"

Nominal capacity (ml) 2.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Locked plunger at the end of

injection

2011

Yes

Location RUP activation RUP Type Plunger lock End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 2.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.0927 Shipping weight (kg) 11.00 Minimum order 200000.00 Pieces per package 1800

Price 1 Over 200000 units: 0.0407 USD Price 2 Over 1000000 units: 0.0399

> USD per unit Year of base price

USD per unit

Over 5000000 units: 0.0387

per unit

Incoterms **FOB**

QUALITY STANDARD

Quality Standard ISO 13485 Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Price 3

Organization name Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Sanzhong® 5ml Product name: IMD-PQS Code: E013-066 Prequalified Status: Date of acceptance: 14 Sep 2011

E013 Appliance type:

Product description: RUP syringe 5ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: Sanzhong® 5ml

Country of Manufacture:

Address: No. 228, Weiyi Road Economic Development Zone 239300

> Tianchang China

+86 550 7308592 Telephone: Email: marshall988@163.net Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.20 **Needle Size** Other **Needle Fixation** Detached Needle Size (Other) 22G x 1 1/4"

Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Locked plunger at end of

injection

2011

Location RUP activation RUP Type Plunger lock End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 22G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 5.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping weight (kg) 11.00

1200 Minimum order Pieces per package 200000.00

Price 1 Over 200000 units: 0.0421 USD Price 2 Over 1000000 units: 0.0412

> USD per unit per unit

Over 5000000 units: 0.0400 Year of base price USD per unit

Incoterms **FOB**

QUALITY STANDARD

Price 3

Shipping volume (m3)

Quality Standard ISO 13485 Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

0.075

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-067 Prequalified Status: Date of acceptance: 14 Sep 2011

E013 Appliance type:

Product description: RUP syringe 10ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: Sanzhong® 10ml

Country of Manufacture:

Address: No. 228, Weiyi Road Economic Development Zone 239300

> Tianchang China

+86 550 7308592 Telephone: Email: marshall988@163.net Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) 0.50 **Needle Size** Other **Needle Fixation** Detached Needle Size (Other) 21G x 1 1/2"

Nominal capacity (ml) 10.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Locked plunger at the end of

injection

2011

Location RUP activation RUP Type Plunger lock End of injection

RUP Needle Fixation Not Fixed **RUP Needle Sizes** 21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 10.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.075 Shipping weight (kg) 14.00 1200 Minimum order 200000.00 Pieces per package

Price 1 Over 200,000 units: 0.0556 USD Price 2 Over 1,000,000 units: 0.0545

> USD per unit Year of base price

Price 3 Over 5,000,000 units: 0.0529

USD per unit

Incoterms **FOB**

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 Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

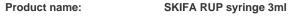
China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

RUP syringe 3ml



IMD-PQS Code: E013-069 Status: Prequalified Date of acceptance: 12 Jan 2011

E013 Appliance type:

Product description:

Manufacturer: Mitra Rajawali Banjaran, PT Manufacturers Reference: SKIFA RUP syringe 3ml

Country of Manufacture: Indonesia

Address: JL. Raya Banjaran KM16 Bandung, Jawa Barat Indonesia

Indonesia

Telephone: +62 22 594 0151

Email: nurasfiyahqo@gmail.com Website address: http://www.mrb.co.id

Valid until: 31 May 2025

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other 0.10 **Needle Size (Other)** 23G x 32mm **Needle Fixation** Detached

Nominal capacity (ml) 3.00 **Packaging & Sterility** Yes

Assurance

Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger locked at end of

injection

RUP Type Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 3.00 **RUP plunger Aspiration** Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking No

PRICE AND SHIPPING

Other needle size options

0.17 15.00 Shipping volume (m3) Shipping weight (kg) Pieces per package 2000 20000.00 Minimum order Price 1 upon request to manufacturer Year of base price 2011

Incoterms **EXW**

QUALITY STANDARD

Quality Standard Quality standard (Other) ISO 9001 ISO 13485;Other

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS VP(s): ISO 7886-4

PRODUCT SITES

Organization name Mitra Rajawali Banjaran, PT

Address JL. Raya Banjaran KM16 Bandung, Jawa Barat Indonesia

Indonesia

Current PQS status: Prequalified Valid until: 31 May 2025





E013: Injection devices for therapeutic purposes

RUP 10ml Product name: IMD-PQS Code: E013-073 Status: Prequalified Date of acceptance: 18 Jul 2012 E013 Appliance type:

Product description: RUP syringe 10ml

Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: RUP 10ml

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China

China

Telephone: +86 (510)3777555 Email: mike@chinasyringe.com Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PRODUCT 1	SPECIFIC	ATIONS -	MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

10.00

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 21G x 1 1/2" **Needle Fixation** Fixed

> Packaging & Sterility **Assurance**

Yes

Other needle size options Yes Plunger aspiration Yes **Number of pieces** 3.00 **RUP** mechanism Plunger lock and break

RUP Type Plunger lock Location RUP activation End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 10.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Nominal capacity (ml)

Shipping volume (m3) 0.12 Shipping weight (kg) 13.00 Pieces per package 1200 Minimum order 200000.00 Price 1 Year of base price 2012 Upon request to manufacturer

Incoterms **FOB**

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 Wuxi Yushou Medical Appliances Co., Ltd

Address No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu Province China

China

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



Status: Prequalified Date of acceptance: 25 Jun 2012

E013 Appliance type:

Product description: RUP retractable syringe 1ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: RUP retractable syringe 1ml

Address: No. 228, Weiyi Road Economic Development Zone 239300

> Tianchang China

Telephone: +86 550 7308592 marshall988@163.net Email: Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 27G x 1/2" **Needle Fixation** Detached

Packaging & Sterility Nominal capacity (ml) 1.00

Assurance

Plunger aspiration

Other needle size options Yes **Number of pieces** 3.00 **RUP** mechanism

Plunger hooked to inner hub, retraction hub and needle,

plunger break

Yes

RUP Type Plunger lock **Location RUP activation** End of injection

RUP Needle Sizes RUP Needle Fixation Fixed 27G x 3/8" (10 mm)

RUP Nominal Capacity (ml) 1.00 **RUP** plunger Aspiration Multiple

RUP Primary Packaging Blister pack **RUP Sub-category** Retractable RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.072 Shipping weight (kg) 10.00 Pieces per package 2000 Minimum order 200000.00 Price 1 Upon request to manufacturer Year of base price 2012

Incoterms **FOB**

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 Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-075 Status: Prequalified Date of acceptance: 25 Jun 2012

E013 Appliance type:

Product description: RUP retractable syringe 2ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: RUP retractable syringe 2ml

Address: No. 228, Weiyi Road Economic Development Zone 239300

> Tianchang China

Telephone: +86 550 7308592 marshall988@163.net Email: Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

PRODUCT 1	SPECIFICA	TIONS -	MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other 0.10 **Needle Size (Other)** 23G x 1" **Needle Fixation** Detached Yes

2.00 **Packaging & Sterility** Nominal capacity (ml)

Assurance

Year of base price

Plunger aspiration

Number of pieces 3.00 **RUP** mechanism Plunger hooked to inner syringe

hub, retraction inner hub and

needle, plunger break

RUP Type Plunger lock **Location RUP activation** End of injection

RUP Needle Sizes RUP Needle Fixation Not Fixed 21G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 2.00 **RUP** plunger Aspiration Multiple

RUP Primary Packaging Blister pack **RUP Sub-category** Retractable RUP

CE marking Yes

PRICE AND SHIPPING

Other needle size options

Shipping volume (m3) 0.0927 Shipping weight (kg) 11.00 Pieces per package 1800 Minimum order 200000.00

Price 1 Upon request to manufacturer

Yes

Incoterms **FOB**

QUALITY STANDARD

Quality Standard ISO 13485 Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

2012

PRODUCT SITES

Organization name Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



IMD-PQS Code:E013-076Status:PrequalifiedDate of acceptance:25 Jun 2012

Appliance type: E013

Product description: RUP retractable syringe 5ml

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference: RUP retractable syringe 5ml

Address: No. 228, Weiyi Road Economic Development Zone 239300

Tianchang China

Telephone: +86 550 7308592

Email: marshall988@163.net

Website address: http://www.tkmedical.com

Valid until: 31 May 2026

Specifications

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) 0.20 Needle Size Other

Needle Size (Other)22G x 1 1/4"Needle FixationDetachedNominal capacity (ml)5.00Packaging & SterilityYes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismPlunger hooked in inner hub,

hub and needle retraction,

plunger break

RUP Type Plunger lock Location RUP activation End of injection

RUP Needle Fixation Not Fixed **RUP Needle Sizes** 22G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 5.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Retractable RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3)0.075Shipping weight (kg)11.00Pieces per package1200Minimum order200000.00

Price 1 Upon request to manufacturer Year of base price 2012

Incoterms FOB

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 Anhui Tiankang Medical Technology Co., Ltd

Address No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



RUP retractable syringe 10ml

IMD-PQS Code:

E013-077 Prequalified

Status:

Date of acceptance:

25 Jun 2012

Appliance type:

E013

Product description:

RUP retractable syringe 10ml

Manufacturer:

Anhui Tiankang Medical Technology Co., Ltd

Manufacturers Reference:

RUP retractable syringe 10ml

Address:

No. 228, Weiyi Road Economic Development Zone 239300

Tianchang

China

Telephone: Email:

Website address:

marshall988@163.net

+86 550 7308592

31 May 2026

http://www.tkmedical.com

Valid until:

Specifications

PRODUCT	SPECIFICATIONS	- MAIN
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Intended purpose Medication variable dose Restrictive use for

None

Graduations (ml)

Number of pieces

variable dose reconstitution

administration; Medication

Needle Size Needle Fixation

Other Detached

Needle Size (Other) Nominal capacity (ml) 21G x 1 1/2" 10.00

Packaging & Sterility

Assurance

Yes

Other needle size options

Yes 3.00 Plunger aspiration **RUP** mechanism

Plunger hooked to inner hub,

hub and needle retraction,

plunger break

RUP Type

Plunger lock Not Fixed

Location RUP activation

RUP Needle Sizes

End of injection

RUP Nominal Capacity (ml)

10.00

RUP plunger Aspiration

21G x 1 1/2" (38 mm) Multiple

RUP Primary Packaging

RUP Needle Fixation

Blister pack

RUP Sub-category

Retractable RUP

CE marking

Yes

PRICE AND SHIPPING

Pieces per package

Shipping volume (m3)

0.075 1200

Shipping weight (kg)

14.00 200000.00

Price 1

Upon request to manufacturer

ISO 13485

Year of base price

Minimum order

2012

Incoterms

FOB

QUALITY STANDARD

Specification Reference

Applicable PQS specification: ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Quality Standard

Organization name

Anhui Tiankang Medical Technology Co., Ltd

Address

No. 228, Weiyi Road Economic Development Zone 239300 Tianchang

China

Current PQS status:

Prequalified

Valid until:

31 May 2026



E013: Injection devices for therapeutic purposes



Appliance type:

Product description: RUP syringe 3ml Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: Yeso-med 3ml

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

> Province China China

Telephone: +86 (510)3777555 Email: mike@chinasyringe.com Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Andread Section 1

Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None
Graduations (ml)	0.10	Needle Size	Other
Needle Size (Other)	23G x 1"	Needle Fixation	Fixed
Nominal capacity (ml)	3.00	Packaging & Sterility Assurance	Yes

Other needle size options Yes Plunger aspiration **Number of pieces** 3.00 **RUP** mechanism

plunger lock and break **RUP Type** Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 3.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.11 12.00 Shipping weight (kg) Pieces per package 2400 Minimum order 200000.00 Price 1 Year of base price 2012 Upon request to manufacturer

Incoterms **FOB**

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 Wuxi Yushou Medical Appliances Co., Ltd

Address No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu Province China

China

Current PQS status: Valid until: 31 May 2026 Prequalified



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-084 Prequalified Status: 11 Feb 2012 Date of acceptance:

E013 Appliance type:

Product description: RUP syringe 2ml

Manufacturer: AMSON VACCINES & PHARMA (PVT) LTD.

Manufacturers Reference: Apple K1 RUP 2ml

Address: 115, Industrial Triangle, Kahuta road, Islamabad Pakistan

Pakistan

Telephone: +92 51 4492022

Email: naveed@amson.org.pk Website address: www.amson.org.pk Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

Graduations (ml) Needle Size Other 0.10 Detached Needle Size (Other) 23G x 1" **Needle Fixation** Packaging & Sterility Yes

Nominal capacity (ml) 2.00

Assurance

Other needle size options Yes Plunger aspiration

RUP mechanism Number of pieces 3.00 Plunger lock & break at

completion of injection

RUP Type Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 2.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

Yes

CE marking

PRICE AND SHIPPING

Shipping volume (m3) 0.07 8.62 Shipping weight (kg) Pieces per package 1200 Minimum order 100000.00 Price 1 Year of base price 2012 On request to manufacturer

Incoterms FOB

QUALITY STANDARD

Quality Standard Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification: ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

AMSON VACCINES & PHARMA (PVT) LTD. Organization name

Address 115, Industrial Triangle, Kahuta road, Islamabad Pakistan

Pakistan

Current PQS status: Valid until: Prequalified 31 May 2026



E013: Injection devices for therapeutic purposes



Apple K1 RUP 5ml

IMD-PQS Code:

E013-085

Status:

Prequalified

Date of acceptance:

11 Feb 2012

Appliance type:

E013

Product description: Manufacturer:

AMSON VACCINES & PHARMA (PVT) LTD.

Manufacturers Reference:

Apple K1 RUP 5ml

RUP syringe 5ml

Address:

115, Industrial Triangle, Kahuta road, Islamabad Pakistan

Pakistan

Telephone:

+92 51 4492022

Email:

naveed@amson.org.pk

Website address:

www.amson.org.pk

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose

Medication variable dose administration; Medication Restrictive use for

None

Graduations (ml)

variable dose reconstitution 0.20

Other

Needle Size (Other)

23G x 1"

Needle Fixation

Detached

Nominal capacity (ml)

5.00

Packaging & Sterility Assurance

Needle Size

Yes

Other needle size options

Yes

Plunger aspiration

Number of pieces

3.00

RUP mechanism

Plunger lock at completion of

injection

RUP Type

Plunger lock

Location RUP activation

End of injection

RUP Needle Fixation

Not Fixed

RUP Needle Sizes

23G x 1" (25 mm)

RUP Nominal Capacity (ml)

5.00

RUP plunger Aspiration

Multiple

RUP Primary Packaging

Blister pack

RUP Sub-category

CE marking

Yes

Simple RUP

PRICE AND SHIPPING

Shipping volume (m3)

0.09

Shipping weight (kg)

10.47

Pieces per package

1200

Minimum order

100000.00

Price 1 Incoterms

FOB

Year of base price

2012

QUALITY STANDARD

Quality Standard

Other

Quality standard (Other)

Specification Reference

Applicable PQS specification: ISO 7886-4 Applicable PQS

On request to manufacturer

VP(s): ISO 7886-4

ISO 9001

PRODUCT SITES

Organization name

AMSON VACCINES & PHARMA (PVT) LTD.

Address

115, Industrial Triangle, Kahuta road, Islamabad Pakistan

Pakistan

Current PQS status: Prequalified

Valid until:

31 May 2026



E013: Injection devices for therapeutic purposes



Yeso-med 2ml Product name: IMD-PQS Code: F013-086 Prequalified Status: 17 Dec 2012 Date of acceptance: E013

Appliance type: Product description: RUP syringe 2ml

Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: Yeso-med 2ml

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China

China

Telephone: +86 (510)3777555 Email: mike@chinasyringe.com Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATION	NS - MAIN
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Intended purpose Medication variable dose Restrictive use for None

> administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 23G X 25mm **Needle Fixation** Fixed

2.00 Nominal capacity (ml) Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Piston lock upon completion

RUP Type Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 23G x 1" (25 mm)

RUP Nominal Capacity (ml) 2.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.11 Shipping weight (kg) 12.00 Pieces per package 2400 Minimum order 200000.00 Price 1 Year of base price 2012 upon request to manufacturer

Incoterms **FOB**

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 Wuxi Yushou Medical Appliances Co., Ltd

Address No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu Province China

China

Current PQS status: Valid until: Prequalified 31 May 2026





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-087Status:SuspendedDate of acceptance:25 Apr 2013Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-088Status:SuspendedDate of acceptance:25 Apr 2013Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:



E013: Injection devices for therapeutic purposes



PRODUCT SPECIFICATIONS - MAIN

Haiou RUP retractable safety syringe 3ml Product name:

IMD-PQS Code: E013-089 Prequalified Status: Date of acceptance: 06 May 2013

E013 Appliance type:

Product description: RUP retractable syringe 3ml

Manufacturer: Guangdong Haiou Medical Apparatus Co., Ltd Haiou RUP retractable safety syringe 3ml Manufacturers Reference:

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

China

Telephone: +86-663-2758666 market01@haiou.net.cn Email: Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None
Graduations (ml)	0.10	Needle Size	Other
Needle Cire (Other)	22C v 25mm	Needle Eivetien	Fixed

Needle Size (Other) 23G x 25mm **Needle Fixation** Nominal capacity (ml) 3.00 Packaging & Sterility Yes **Assurance**

Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Plunger lock and needle

retraction

RUP Type Location RUP activation End of injection Plunger lock **RUP Needle Fixation** Fixed **RUP Needle Sizes** 23G x 1" (25 mm) **RUP Nominal Capacity (ml)** 3.00 Multiple

RUP plunger Aspiration

RUP Primary Packaging Blister pack

CE marking

Yes

Yes

RUP Sub-category Retractable RUP

PRICE AND SHIPPING

Other needle size options

17.00 Shipping volume (m3) 0.118 Shipping weight (kg) Pieces per package 2400 Minimum order 100000.00 2013 Price 1 Upon request to manufacturer Year of base price

Incoterms **FOB**

QUALITY STANDARD

ISO 13485 Applicable PQS specification: **Quality Standard** Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Guangdong Haiou Medical Apparatus Co., Ltd Organization name

Address Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Haiou RUP retractable safety syringe 5ml Product name:

IMD-PQS Code: E013-090 Status: Prequalified Date of acceptance: 06 May 2013

E013 Appliance type:

Product description: RUP retractable 5ml

Manufacturer: Guangdong Haiou Medical Apparatus Co., Ltd Manufacturers Reference: Haiou RUP retractable safety syringe 5ml

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

China

Telephone: +86-663-2758666 market01@haiou.net.cn Email: Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - M

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 21G x 38mm **Needle Fixation** Fixed

5.00 Nominal capacity (ml) Packaging & Sterility

Assurance

Plunger aspiration

Number of pieces 3.00 **RUP** mechanism

plunger lock and needle

retraction

Yes

RUP Type Location RUP activation Plunger lock End of injection **RUP Needle Fixation** Fixed **RUP Needle Sizes** 21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 5.00 **RUP plunger Aspiration** Multiple

RUP Primary Packaging Retractable RUP Blister pack **RUP Sub-category**

CE marking Yes

Other needle size options

PRICE AND SHIPPING

Shipping volume (m3) 0.122 Shipping weight (kg) 18.00 Pieces per package 1800 Minimum order 100000.00

Price 1 Upon request to manufacturer

Yes

Incoterms **FOB**

2013 Year of base price

QUALITY STANDARD

ISO 13485 Applicable PQS specification: **Quality Standard** Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Guangdong Haiou Medical Apparatus Co., Ltd Organization name

Address Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Haiou RUP retractable syringe 10ml Product name:

IMD-PQS Code: E013-091 Status: Prequalified Date of acceptance: 06 May 2013

E013 Appliance type:

Product description: RUP retractable 10ml

Manufacturer: Guangdong Haiou Medical Apparatus Co., Ltd

Haiou RUP retractable syringe 10ml Manufacturers Reference:

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

China

Telephone: +86-663-2758666 market01@haiou.net.cn Email: Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - M

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 21G x 38mm **Needle Fixation** Fixed

Nominal capacity (ml) 10.00 Packaging & Sterility

Yes

Assurance

Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism

Plunger lock and needle

retraction

Yes

RUP Type Location RUP activation End of injection Plunger lock **RUP Needle Fixation** Fixed **RUP Needle Sizes** 21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 10.00 **RUP plunger Aspiration** Multiple

RUP Primary Packaging Retractable RUP Blister pack **RUP Sub-category**

CE marking Yes

PRICE AND SHIPPING

Other needle size options

17.00 Shipping volume (m3) 0.11 Shipping weight (kg) Pieces per package 1200 Minimum order 100000.00 2013 Price 1 Upon request to manufacturer Year of base price

Incoterms **FOB**

QUALITY STANDARD

ISO 13485 Applicable PQS specification: **Quality Standard** Specification Reference

ISO 7886-4 Applicable PQS VP(s): ISO 7886-4

PRODUCT SITES

Guangdong Haiou Medical Apparatus Co., Ltd Organization name

Address Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China

China

Current PQS status: Prequalified Valid until: 31 May 2026





E013: Injection devices for therapeutic purposes

Product name: OnejectII RUP insulin 1ml

IMD-PQS Code: E013-092 Prequalified Status: Date of acceptance: 06 May 2013 Appliance type: E013

Product description: **RUP Insulin 1ml** Manufacturer: PT Oneject Indonesia Manufacturers Reference: OnejectII RUP insulin 1ml

Address: Sentul Industrial Estate Jl. Olympic Raya Kav B9 Bogor

16810, Indonesia

Indonesia

Telephone: +62 21 879 17 422

niken.permatasari@oneject.co.id Email:

Website address: www.oneject.co.id Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for Insulin administration

administration

0.02 **Needle Size** Other Graduations (ml) Needle Size (Other) **Needle Fixation** Fixed 27G x 3/8" Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration

RUP mechanism **Number of pieces** 3.00 Locked / broken plunger

RUP Type Plunger lock 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 RUP Sub-category** Simple RUP Blister pack

CE marking

Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.051 Shipping weight (kg) 8.23 Pieces per package 1600 Minimum order 16000.00 Price 1 2013 Upon request to manufacturer Year of base price

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 PT Oneject Indonesia

Address Sentul Industrial Estate Jl. Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: OnejectII RUP 3ml

IMD-PQS Code:E013-093Status:PrequalifiedDate of acceptance:06 May 2013

Appliance type: E013

Product description: RUP syringe 3ml

Manufacturer: PT Oneject Indonesia

Manufacturers Reference: OnejectII RUP 3ml

Address: Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor

16810, Indonesia Indonesia

Telephone: +62 21 879 17 422

Email: niken.permatasari@oneject.co.id

Website address: www.oneject.co.id
Valid until: 31 May 2025

Specifications

PRODUCT SPECIFICATIONS - MAIN

3 ml

 Intended purpose
 Medication variable dose administration; Medication
 Restrictive use for administration
 None

variable dose reconstitution

Yes

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)23G x 1 ½"Needle FixationFixedNominal capacity (ml)3.00Packaging & SterilityYes

Assurance

Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism Locked / broken plunger

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes23G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 3.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

CE marking Yes

PRICE AND SHIPPING

Other needle size options

Shipping volume (m3)0.087Shipping weight (kg)12.20Pieces per package1600Minimum order18000.00Price 1Upon request to manufacturerYear of base price2013

Incoterms FOB

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 PT Oneject Indonesia

Address Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status:PrequalifiedValid until:31 May 2025



E013: Injection devices for therapeutic purposes



Product name: Haiou RUP retractable safety syringe 1ml

IMD-PQS Code:E013-096Status:PrequalifiedDate of acceptance:07 Oct 2013Appliance type:E013

Product description: RUP retractable syringe 1ml

Manufacturer:Guangdong Haiou Medical Apparatus Co., LtdManufacturers Reference:Haiou RUP retractable safety syringe 1ml

Address: Nanyuan Industrial Zone, North Liusha, Puning City,

Guangdong Province, China

China

Telephone: +86-663-2758666

Email: market01@haiou.net.cn

Website address: http://www.haiou.net.cn

Valid until: 31 May 2026

Specifications

Current PQS status:

PRODUCT SPECIFICATIONS -	MAIN		
Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None
Graduations (ml)	0.01	Needle Size	Other
Needle Size (Other)	29G x 12mm	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	Plunger locked to needle hub upon completion of injection and needle retraction into barrel
RUP Type	Plunger lock	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	Blister pack	RUP Sub-category	Retractable RUP
CE marking	Yes		
PRICE AND SHIPPING			
Shipping volume (m3)	0.101	Shipping weight (kg)	16.00
Pieces per package	3000	Minimum order	100000.00
Price 1	Upon request	Year of base price	2013
Incoterms	FOB		
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	Guangdong Haiou Medical App	aratus Co., Ltd	
Address	Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong Province, China		

Valid until:

31 May 2026

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

China

Prequalified



E013: Injection devices for therapeutic purposes



Product name: YI XIN RUP 2ml
IMD-PQS Code: E013-097
Status: Prequalified
Date of acceptance: 09 Nov 2013

Appliance type: E013

Product description: RUP syringe 2ml

Manufacturer: Jiangxi Sanxin Medtec Co.,Ltd

Manufacturers Reference: YI XIN RUP 2ml

Address: 999 Fushan Road, Xiaolan Economic Development Zone,

Nanchang, Jiangxi, P.C. 330200 China; People's Republic

China

Telephone: +86 791 85988111

Email: fgb@sanxin-med.com

Website address: www.sanxin-med.com

Valid until: 31 May 2026

Specifications

PRODUCT SITES
Organization name

Current PQS status:

Address

PRODUCT SPECIFICATIONS -	MAIN		
Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None
Vaccine capacity (mL)	3.00	Graduations (ml)	0.10
Needle Size	Other	Needle Size (Other)	25G x 1"
Needle Fixation	Detached	Nominal capacity (ml)	2.00
Packaging & Sterility Assurance	Yes	Other needle size options	Yes
Plunger aspiration	Yes	Number of pieces	3.00
RUP mechanism	Plunger lock	RUP Type	Plunger lock
Location RUP activation	End of injection	RUP Needle Fixation	Not Fixed
RUP Needle Sizes	25G x 1" (25 mm)	RUP Nominal Capacity (ml)	2.00
RUP plunger Aspiration	Multiple	RUP Primary Packaging	Blister pack
RUP Sub-category	Simple RUP	CE marking	Yes
Comments	Secondary package can also contain 2400 syringes Shipping volume (m3): 0.10-0.13		
PRICE AND SHIPPING			
Pieces per package	1800	Minimum order	200000.00
Price 1	Upon request ot manufacturer	Year of base price	2013
Incoterms	FCA		
QUALITY STANDARD			
Quality Standard	ISO 13485;Other	Quality standard (Other)	ISO 9001
Specification Reference	Applicable PQS specification: ISO 7886-4 Applicable PQS VP(s): ISO 7886-4		

999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, P.C. 330200 China;

31 May 2026

Valid until:

Jiangxi Sanxin Medtec Co.,Ltd

People's Republic of

China

Prequalified



E013: Injection devices for therapeutic purposes



YI XIN RUP 5ml Product name: IMD-PQS Code: F013-098 Status: Prequalified 09 Nov 2013 Date of acceptance:

E013 Appliance type:

Product description: RUP syringe 5ml

Manufacturer: Jiangxi Sanxin Medtec Co., Ltd

Manufacturers Reference: YI XIN RUP 5ml

Country of Manufacture:

Address: 999 Fushan Road, Xiaolan Economic Development Zone,

Nanchang, Jiangxi, P.C. 330200 China; People's Republic

Yes

of China

Telephone: +86 791 85988111 Email: fgb@sanxin-med.com Website address: www.sanxin-med.com

Valid until: 31 May 2026

Specifications

PRODUCT:	T SPECIFIC	ATIONS -	MAIN

Medication variable dose Restrictive use for Intended purpose None administration; Medication

variable dose reconstitution

Graduations (ml) **Needle Size** Other 0.20 Needle Size (Other) 25G x 1" **Needle Fixation** Detached Nominal capacity (ml)

5.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

RUP mechanism Number of pieces 3.00 Plunger lock **Location RUP activation RUP Type** Plunger lock End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 25G x 1" (25 mm)

5.00 Multiple **RUP Nominal Capacity (ml) RUP plunger Aspiration RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.1 Shipping weight (kg) 7.00 Pieces per package 1200 Minimum order 200000.00 Price 1 Year of base price 2013 Upon request to manufacturer

Incoterms **FCA**

QUALITY STANDARD

Quality standard (Other) ISO 9001 **Quality Standard** ISO 13485;Other

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Jiangxi Sanxin Medtec Co.,Ltd

Address 999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, P.C. 330200 China;

People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: Medeco® Inject RUP 3ml

IMD-PQS Code:E013-099Status:PrequalifiedDate of acceptance:11 Jul 2013Appliance type:E013

Product description: RUP syringe 3ml

Manufacturer: Abu Dhabi Medical Devices Co. L.L.C

Manufacturers Reference: Medeco® Inject RUP 3ml

Address: MUSSAFAH INDUSTRIAL AREA, M-43, PLOT 124, 30485,

Yes

ABU DHABI United Arab Emirates

Telephone: +971-2-6199100

Email: info@admd.ae

Website address: http://www.admd.ae

Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATIONS -	· MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Nominal capacity (ml) 2.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismValve in needle hubRUP TypeOtherLocation RUP activationStart of injectionRUP Needle FixationFixedRUP Needle Sizes21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml) 3.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

CE marking Yes

Comments Nominal capacity 2ml, graduations to 3ml Available in two carton sizes 900pcs and 1,600pcs

Shipping volume (m3): 900pcs 0.074m3, 1,600pcs 0.1m3 Shipping weight (kg): 900 pcs 4.2kg,

1,600pcs 11.6kg

PRICE AND SHIPPING

Pieces per package900Minimum order1000000.00Price 1Upon request to manufacturerYear of base price2013

Incoterms EXW

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification: ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Abu Dhabi Medical Devices Co. L.L.C

Address MUSSAFAH INDUSTRIAL AREA, M-43, PLOT 124, 30485, ABU DHABI

United Arab Emirates

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: Medeco® Inject RUP 5ml

IMD-PQS Code:E013-100Status:PrequalifiedDate of acceptance:11 Jul 2013Appliance type:E013

Product description: RUP syringe 5ml

Manufacturer: Abu Dhabi Medical Devices Co. L.L.C

Manufacturers Reference: Medeco® Inject RUP 5ml

Address: MUSSAFAH INDUSTRIAL AREA, M-43, PLOT 124, 30485,

ABU DHABI United Arab Emirates

Telephone: +971-2-6199100

Email: info@admd.ae

Website address: http://www.admd.ae

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)21G x 1 1/2"Needle FixationFixed

Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismValve in needle hubRUP TypeOtherLocation RUP activationStart of injectionRUP Needle FixationFixedRUP Needle Sizes21G x 1 1/2" (38 mm)

RUP Nominal Capacity (ml)5.00RUP plunger AspirationMultipleRUP Primary PackagingBlister packRUP Sub-categorySimple RUP

CE marking Yes

Comments Available in two carton sizes 800pcs and 1800 pcs Shipping volume (m3): 800 pcs 0.073m3, 1,800

0.1m3 Shipping weight (kg): 800 pcs 4.9kg, 1,800 pcs 16.5kg

PRICE AND SHIPPING

Pieces per package 800 Minimum order 1000000.00

Price 1 Upon request to manufacturer Year of base price 2013

Incoterms EXW

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Abu Dhabi Medical Devices Co. L.L.C

Address MUSSAFAH INDUSTRIAL AREA, M-43, PLOT 124, 30485, ABU DHABI

United Arab Emirates

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Yixin retractable 1ml Product name:

IMD-PQS Code: F013-101 Prequalified Status: 12 Mar 2013 Date of acceptance:

E013 Appliance type:

Product description: RUP retractable 1ml

Manufacturer: Jiangxi Sanxin Medtec Co., Ltd

Manufacturers Reference: Yixin retractable 1ml

Address: 999 Fushan Road, Xiaolan Economic Development Zone,

Nanchang, Jiangxi, P.C. 330200 China; People's Republic

China

+86 791 85988111 Telephone: Email: fgb@sanxin-med.com Website address: www.sanxin-med.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration: Medication

variable dose reconstitution

Graduations (ml) 0.02 Needle Size Other Needle Size (Other) **Needle Fixation** Fixed 29G x 1/2"

Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism Needle retraction into barrel

RUP Type Location RUP activation Other 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 Retractable RUP Blister pack **RUP Sub-category**

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.11 Shipping weight (kg) 15.50 Pieces per package 3000 Minimum order 100000.00

2013 Price 1 Upon request to manufacturer Year of base price

Incoterms **FCA**

QUALITY STANDARD

ISO 13485 Applicable PQS specification: **Quality Standard** Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Jiangxi Sanxin Medtec Co.,Ltd

Address 999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, P.C. 330200 China;

People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: Yixin retractable 3ml

IMD-PQS Code:E013-102Status:PrequalifiedDate of acceptance:12 Mar 2013

Appliance type: E013

Product description: RUP retractable 3ml

Manufacturer: Jiangxi Sanxin Medtec Co.,Ltd

Manufacturers Reference: Yixin retractable 3ml

Address: 999 Fushan Road, Xiaolan Economic Development Zone,

Nanchang, Jiangxi, P.C. 330200 China; People's Republic

China

Telephone: +86 791 85988111

Email: fgb@sanxin-med.com

Website address: www.sanxin-med.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration: Medication

variable dose reconstitution

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)25G x 1"Needle FixationFixedNominal capacity (ml)3.00Packaging & SterilityYes

Accurance

Assurance

Year of base price

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismNeedle retraction into barrel

RUP TypeOtherLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes25G x 1" (25 mm)

RUP Nominal Capacity (ml) 3.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Retractable RUP

CE marking Yes

JE marking

PRICE AND SHIPPING

Shipping volume (m3) 0.15 Shipping weight (kg) 17.00

Pieces per package 2400 Minimum order 100000.00

Price 1 Upon request to manufacturer

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

2013

PRODUCT SITES

Organization name Jiangxi Sanxin Medtec Co.,Ltd

Address 999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, P.C. 330200 China;

People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: YIXIN® retractable 5ml

IMD-PQS Code:E013-103Status:PrequalifiedDate of acceptance:12 Mar 2013

Appliance type: E013

Product description: RUP retractable 5ml

Manufacturer: Jiangxi Sanxin Medtec Co.,Ltd

Manufacturers Reference: YIXIN® retractable 5ml

Address: 999 Fushan Road, Xiaolan Economic Development Zone,

Nanchang, Jiangxi, P.C. 330200 China; People's Republic

China

Telephone: +86 791 85988111

Email: fgb@sanxin-med.com

Website address: www.sanxin-med.com

Valid until: 31 May 2026

Specifications

PRODUCT 1	SPECIFICAT	IONS - MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml)0.20Needle SizeOtherNeedle Size (Other)23G x 1"Needle FixationDetached

Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismNeedle retraction into barrel

RUP TypeOtherLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes23G x 1" (25 mm)

RUP Nominal Capacity (ml) 5.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Retractable RUP

CE marking Yes

Comments Primary packaging: Paper blister pack

PRICE AND SHIPPING

QUALITY STANDARD

Shipping volume (m3)0.09Shipping weight (kg)14.00Pieces per package1200Minimum order100000.00Price 1Upon request to manufacturerYear of base price23013

Incoterms FCA

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Jiangxi Sanxin Medtec Co.,Ltd

Address 999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, P.C. 330200 China;

People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

RUP syringe 2mL Product name:

IMD-PQS Code: E013-105 Prequalified Status: Date of acceptance: 07 Jan 2015 E013 Appliance type:

Product description: RUP 2mL

Manufacturer: Sanavita Pharmaceuticals GMBH

RUP syringe 2mL Manufacturers Reference: Address: Spaldingstr. 110B

> Hamburg Hamburg Germany

+49 40 730 8853-0 Telephone:

Email: guenter.kunde@sanavita.net

Website address: www.sanavita.net Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

variable dose reconstitution

0.20 Needle Size Other Graduations (ml)

Needle Size (Other) 21Gx1 1/2" (38mm) **Needle Fixation** Fixed Syringe material(s) Polypropylene Nominal capacity (ml) 2.00 Other needle size options

Packaging & Sterility

Yes **Assurance**

Plunger aspiration Yes **Number of pieces** 3.00

RUP mechanism **RUP Type** Plunger lock Plunger lock **Location RUP activation RUP Needle Fixation** End of injection Fixed **RUP Needle Sizes** 21G x 1 1/2" (38 mm) **RUP Nominal Capacity (ml)** 2.00

Multiple **RUP Primary Packaging RUP plunger Aspiration** Blister pack

RUP Sub-category Simple RUP **CE** marking Yes

PRICE AND SHIPPING

13.00 Shipping volume (m3) 0.127 Shipping weight (kg) Pieces per package 3000 Minimum order 3000.00 2016 Price 1 Upon request to manufacturer Year of base price

Incoterms **FCA**

QUALITY STANDARD

ISO 13485 Applicable PQS specification: **Quality Standard** Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

Yes

PRODUCT SITES

Organization name Sanavita Pharmaceuticals GMBH

Address Spaldingstr. 110B

Hamburg Hamburg Germany

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

RUP syringe 5mL Product name:

IMD-PQS Code: E013-106 Prequalified Status: Date of acceptance: 07 Jan 2015 E013 Appliance type:

Manufacturer: Sanavita Pharmaceuticals GMBH

RUP syringe 5mL Manufacturers Reference: Address: Spaldingstr. 110B

> Hamburg Hamburg Germany

RUP 5mL

+49 40 730 8853-0 Telephone:

Email: guenter.kunde@sanavita.net

Website address: www.sanavita.net Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

Product description:

variable dose reconstitution

0.20 Needle Size Graduations (ml)

Needle Size (Other) 21Gx1 1/2" (38mm) **Needle Fixation** Fixed Syringe material(s) Polypropylene Nominal capacity (ml) 5.00 Other needle size options Yes Yes

Packaging & Sterility

Assurance

Plunger aspiration Yes **Number of pieces** 3.00

RUP Type RUP mechanism Plunger lock Plunger lock **Location RUP activation RUP Needle Fixation** End of injection Fixed **RUP Needle Sizes** 21G x 1 1/2" (38 mm) **RUP Nominal Capacity (ml)** 5.00 Multiple **RUP Primary Packaging RUP plunger Aspiration** Blister pack

RUP Sub-category Simple RUP **CE** marking Yes

PRICE AND SHIPPING

13.00 Shipping volume (m3) 0.137 Shipping weight (kg) Pieces per package 1800 Minimum order 1800.00 2016 Price 1 Upon request to manufacturer Year of base price

Incoterms **FCA**

QUALITY STANDARD

ISO 13485 Applicable PQS specification: **Quality Standard** Specification Reference

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

Other

PRODUCT SITES

Organization name Sanavita Pharmaceuticals GMBH

Address Spaldingstr. 110B

Hamburg Hamburg Germany

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Product name: Oneject II RUP Syringe 2 mL

IMD-PQS Code:E013-108Status:PrequalifiedDate of acceptance:21 Sep 2015

Appliance type: E013

Product description:RUP Syringe 2 mLManufacturer:PT Oneject IndonesiaManufacturers Reference:Oneject II RUP Syringe 2 mL

Address: Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor

16810, Indonesia Indonesia

Telephone: +62 21 879 17 422

Email: niken.permatasari@oneject.co.id

Website address: www.oneject.co.id
Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication fixed dose Restrictive use for Therapeutic use

administration

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)23G x 1 ¼"Needle FixationFixedNominal capacity (ml)2.00Packaging & SterilityYes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism Locked / broken plunger

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationFixedRUP Needle Sizes23G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 2.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

CE marking Yes

on marking

PRICE AND SHIPPING

Shipping volume (m3)0.09Shipping weight (kg)10.60Pieces per package1600Minimum order1600.00Price 1Upon request to manufacturerYear of base price2015

Incoterms FOE

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name PT Oneject Indonesia

Address Sentul Industrial Estate Jl.Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes

Oneject II RUP Syringe 5 mL Product name:

IMD-PQS Code: E013-109 Status: Prequalified Date of acceptance: 21 Sep 2015

Appliance type: E013

Product description: RUP syringe 5 mL Manufacturer: PT Oneject Indonesia Manufacturers Reference: Oneject II RUP Syringe 5 mL

Address: Sentul Industrial Estate Jl. Olympic Raya Kav B9 Bogor

> 16810, Indonesia Indonesia

Telephone: +62 21 879 17 422

Email: niken.permatasari@oneject.co.id

Website address: www.oneject.co.id Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication fixed dose Restrictive use for Therapeutic use

administration

Graduations (ml) **Needle Size** Other 0.10 Detached Needle Size (Other) 21G x 1 1/2" **Needle Fixation** Yes

Nominal capacity (ml) 5.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration

Number of pieces 3.00 **RUP** mechanism Locked / broken plunger

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 RUP Sub-category** Simple RUP Blister pack

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.08 Shipping weight (kg) 12.00 Pieces per package 1200 Minimum order 1200.00 Price 1 2015 Upon request to manufacturer Year of base price

Incoterms

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

ISO 7886-4 Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name PT Oneject Indonesia

Address Sentul Industrial Estate Jl. Olympic Raya Kav B9 Bogor 16810, Indonesia

Indonesia

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: SKIFA RUP 1ml
IMD-PQS Code: E013-110
Status: Prequalified
Date of acceptance: 05 Jul 2015
Appliance type: E013
Product description: RUP 1ml

Manufacturer: Mitra Rajawali Banjaran, PT

Manufacturers Reference: SKIFA RUP 1ml

Address: JL. Raya Banjaran KM16 Bandung, Jawa Barat Indonesia

Indonesia

Telephone: +62 22 594 0151

Email: nurasfiyahqo@gmail.com
Website address: http://www.mrb.co.id
Valid until: 31 May 2025

Specifications

Current PQS status:

PRODUCT SPECIFICATIONS - MAIN				
Intended purpose	Medication variable dose administration; Medication variable dose reconstitution	Restrictive use for	None	
Vaccine capacity (mL)	1.00	Graduations (ml)	0.05	
Needle Size	Other	Needle Size (Other)	26G x ½ "	
Needle Fixation	Detached	Nominal capacity (ml)	1.00	
Packaging & Sterility Assurance	Yes	Other needle size options	Yes	
Plunger aspiration	Yes	Number of pieces	3.00	
RUP mechanism	Hooked to hub at end of injection	RUP Type	Other	
Location RUP activation	End of injection	RUP Needle Fixation	Not Fixed	
RUP Needle Sizes	26G x 3/8" (10 mm)	RUP Nominal Capacity (ml)	1.00	
RUP plunger Aspiration	Multiple	RUP Primary Packaging	Blister pack	
RUP Sub-category	Simple RUP	CE marking	Yes	
PRICE AND SHIPPING				
Shipping volume (m3)	0.142	Shipping weight (kg)	11.88	
Pieces per package	100	Minimum order	10000.00	
Price 1	24cts	Year of base price	2015	
Incoterms	EXW			
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 Address				

Valid until:

31 May 2025

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

Prequalified



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-111 Status: Prequalified 05 Jul 2015 Date of acceptance: Appliance type: E013

Manufacturer: Mitra Rajawali Banjaran, PT

Manufacturers Reference: SKIFA RUP 5ml

Address: JL. Raya Banjaran KM16 Bandung, Jawa Barat Indonesia

Indonesia

RUP 5ml

Telephone: +62 22 594 0151

Email: nurasfiyahqo@gmail.com Website address: http://www.mrb.co.id Valid until: 31 May 2025

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None administration; Medication

Product description:

variable dose reconstitution

Graduations (ml) Needle Size Other 0.20

Needle Fixation Detached Needle Size (Other) 22G x 1 1/2" Packaging & Sterility Yes

Nominal capacity (ml) 5.00 Assurance

No

Other needle size options Yes Plunger aspiration

RUP mechanism Number of pieces 3.00 Hooked in hub at end of

injection

RUP Type Other **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 22G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 5.00 **RUP** plunger Aspiration Multiple

RUP Primary Packaging Plastic ribbon **RUP Sub-category** Simple RUP

PRICE AND SHIPPING

CE marking

Shipping volume (m3) 0.71 Shipping weight (kg) 14.02 Pieces per package 100 Minimum order 10000.00 Price 1 Year of base price 2015 28 cts

Incoterms EXW

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

> ISO 7886-4 Applicable PQS VP(s): ISO 7886-4

PRODUCT SITES

Mitra Rajawali Banjaran, PT Organization name

JL. Raya Banjaran KM16 Bandung, Jawa Barat Indonesia Address

Indonesia

Current PQS status: Valid until: Prequalified 31 May 2025



E013: Injection devices for therapeutic purposes



IMD-PQS Code: E013-115 Prequalified Status: 13 Nov 2017 Date of acceptance:

E013 Appliance type:

Product description: RUP Syringe 3ml

Manufacturer: International Company for Medical Necessities Manufacturers Reference: Smooth Inject Re-Use Prevention Syringe 3ml

Address: Industrial Zone Block No. 19&67 Abu Tig Assuit Egypt

Telephone: +2 (088) 49 50200 - 202 - 250

Email: mak@medical-ico.com

Website address: www.medical-ico.com & aak@medical-ico.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIF	ICATIONS - MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration

Graduations (ml) 0.10 **Needle Size** Other Detached Needle Size (Other) 23G x 1 1/4 **Needle Fixation** Packaging & Sterility Yes

Nominal capacity (ml) 3.00

Yes

Assurance

Yes Plunger aspiration

Number of pieces 3.00 **RUP** mechanism Locking plunger **RUP Type** Plunger lock **Location RUP activation** End of injection Not Fixed **RUP Needle Sizes RUP Needle Fixation** 23G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 3.00 Multiple **RUP** plunger Aspiration **RUP Primary Packaging** Simple RUP Blister pack **RUP Sub-category**

CE marking Yes

Needle fixation: Detachable Plunger aspiration: Multiple Title: RUP Syringe 3ml Primary packaging: Comments

Price 2

Paper blister pack Needle size: 23G x 1 1/4

PRICE AND SHIPPING

Other needle size options

Shipping weight (kg) Shipping volume (m3) 0.08419 11.55 Pieces per package 2200 Minimum order 500000.00

Price 3 10m US\$ 0.025 Year of base price 2019

EXW Incoterms

QUALITY STANDARD

Price 1

Quality Standard ISO 13485 Specification Reference Applicable PQS specification:

7886-4 Applicable PQS VP(s):

1m US\$ 0.027

PRODUCT SITES

Organization name International Company for Medical Necessities

Address Industrial Zone Block No. 19&67 Abu Tig Assuit Egypt

100,000 US\$ 0.028

Egypt

Current PQS status: Prequalified Valid until: 31 May 2026





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-116Status:PrequalifiedDate of acceptance:13 Nov 2017

Manufacturer: 0013X00003VGpWzQAL

Valid until: 31 May 2025

Specifications

Current PQS status: Prequalified Valid until: 31 May 2025



E013: Injection devices for therapeutic purposes



IMD-PQS Code:E013-117Status:PrequalifiedDate of acceptance:13 Nov 2017

Appliance type: E013

Product description: RUP Syringe 10ml

Manufacturer:International Company for Medical NecessitiesManufacturers Reference:Smooth Inject Re-Use Prevention Syringe 10ml

Address: Industrial Zone Block No. 19&67 Abu Tig Assuit Egypt

Yes

Egyp

Telephone: +2 (088) 49 50200 - 202 - 250

Email: mak@medical-ico.com

Website address: www.medical-ico.com & aak@medical-ico.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication variable dose Restrictive use for None

administration

Graduations (ml)0.20Needle SizeOtherNeedle Size (Other)21 G x 1.1/4"Needle FixationDetached

Nominal capacity (ml) 10.00 Packaging & Sterility

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismLocked plungerRUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes22G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml)10.00RUP plunger AspirationMultipleRUP Primary PackagingBlister packRUP Sub-categorySimple RUP

CE marking Yes

PRICE AND SHIPPING

Shipping volume (m3)0.084Shipping weight (kg)10.00Pieces per package1000Minimum order500000.00

Price 1 100,000 US\$ 0.037 **Price 2** 1m US\$ 0.036

Price 3 10m US\$ 0.035 **Year of base price** 2019

Incoterms EXW

QUALITY STANDARD

Specification Reference Applicable PQS specification: 7886-4 Applicable PQS VP(s):

PRODUCT SITES

Organization name International Company for Medical Necessities

Address Industrial Zone Block No. 19&67 Abu Tig Assuit Egypt

Egypt

Current PQS status:PrequalifiedValid until:31 May 2026





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-118Status:SuspendedDate of acceptance:14 Aug 2018Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-119Status:SuspendedDate of acceptance:14 Aug 2018Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:



E013: Injection devices for therapeutic purposes



Hongda 1ml RUP syringe Product name:

IMD-PQS Code: E013-120 Prequalified Status: 10 Dec 2018 Date of acceptance:

E013 Appliance type:

Product description: 1ml RUP syringe

Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd

Manufacturers Reference: Hongda 1ml RUP syringe

Address: 39 South Shengi Road Jinxian county, Nanchang City

Jiangxi province China; People's Republic of

China

Telephone: +86 791 85628828 hongda008@jxhd.cn Email: Website address: http://www.jxhd.cn Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN

Intended purpose Medication fixed dose Restrictive use for None

administration; Medication

variable dose

Yes

administration; Medication variable dose reconstitution

Graduations (ml) 0.02 **Needle Size** Other Needle Size (Other) 26G 5/8" **Needle Fixation** Detached Yes

Nominal capacity (ml) 1.00 Packaging & Sterility

Assurance

Plunger aspiration Yes

RUP mechanism **Number of pieces** 3.00 Gasket locked/broken plunger

RUP Type Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 26G x 3/8" (10 mm)

RUP Nominal Capacity (ml) 1.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

Other needle size options

Shipping volume (m3) 0.0979 Shipping weight (kg) 19.00 1500 Minimum order 100000.00

Price 1 Year of base price 2017 price on request

Incoterms **FOB**

QUALITY STANDARD

PRICE AND SHIPPING

Pieces per package

Quality Standard ISO 13485 Specification Reference Applicable PQS specification:

7886-4 Applicable PQS VP(s):

PRODUCT SITES

Jiangxi Hongda Medical Equipment Group Ltd Organization name

Address 39 South Shengi Road Jinxian county, Nanchang City Jiangxi province China; People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Hongda 10ml RUP syringe SD10L Product name:

IMD-PQS Code: E013-121 Status: Prequalified 10 Dec 2018 Date of acceptance:

E013 Appliance type:

Product description: 10ml RUP syringe

Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd

Manufacturers Reference: Hongda 10ml RUP syringe SD10L

Address: 39 South Shengi Road Jinxian county, Nanchang City

Jiangxi province China; People's Republic of

Yes

China

Telephone: +86 791 85628828 hongda008@jxhd.cn Email: Website address: http://www.jxhd.cn Valid until: 31 May 2026

Specifications

Nominal capacity (ml)

Other needle size options

PRODUCT	SPECIFICATIONS -	· MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 21G x 1 1/2" **Needle Fixation** Detached

> Packaging & Sterility **Assurance**

Plunger aspiration

Number of pieces 3.00 **RUP** mechanism locked gasket/plunger 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) 10.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

Comments Needle at side available Pieces per carton:1500 or 1200. Different pieces per carton are available.

Graduations: with scale interval of 0.5ml and 2ml increment between graduation lines to be

numbered

10.00

Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.102 Shipping weight (kg) 16.00 Pieces per package 1500 Minimum order 100000.00 Price 1 Year of base price 2017 price on request

Incoterms **FOB**

QUALITY STANDARD

Quality Standard ISO 13485 **Specification Reference** Applicable PQS specification:

7886-4 Applicable PQS VP(s):

PRODUCT SITES

Organization name Jiangxi Hongda Medical Equipment Group Ltd

Address 39 South Shengi Road Jinxian county, Nanchang City Jiangxi province China; People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: 2ml LS RUP 23X1 AN Bawal

IMD-PQS Code:E013-122Status:PrequalifiedDate of acceptance:16 May 2019

Appliance type: E013

Product description: 2ml RUP 23X1 syringe

Manufacturer: Becton Dickinson

Manufacturers Reference: 2ml LS RUP 23X1 AN Bawal

Address: Crtra. Mequinenza (N-211) S/N, 22520, Fraga (Huesca)

Spain

Telephone: +34 974470900

Email: kathy.cooman@bd.com

Website address: http://www.bd.com

Valid until: 31 May 2026

Specifications

Intended purpose Medication fixed dose Restrictive use for None administration

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)24x1Needle FixationDetached

Nominal capacity (ml) 2.00 Packaging & Sterility

Assurance

Yes

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism locked and breaking plunger

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes24G x 1" (25 mm)

RUP Nominal Capacity (ml)2.00RUP plunger AspirationMultipleRUP Primary PackagingBlister packCE markingYes

PRICE AND SHIPPING

Pieces per package2400Minimum order48000.00Price 1price on requestYear of base price2019

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

Applicable PQS VP(s):

PRODUCT SITES

Organization name Becton Dickinson

Address Crtra. Mequinenza (N-211) S/N, 22520, Fraga (Huesca)

United States of America

Current PQS status:PrequalifiedValid until:31 May 2026



E013: Injection devices for therapeutic purposes



Honga RUP 3ml syringe SD03L Product name:

IMD-PQS Code: E013-124 Status: Prequalified 10 Dec 2018 Date of acceptance:

E013 Appliance type:

Product description: RUP 3ml syringe

Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd

Manufacturers Reference: Honga RUP 3ml syringe SD03L

Address: 39 South Shengi Road Jinxian county, Nanchang City

Jiangxi province China; People's Republic of

China

Telephone: +86 791 85628828 hongda008@jxhd.cn Email: Website address: http://www.jxhd.cn Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATION	NS - MAIN
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Intended purpose Medication variable dose Restrictive use for None

administration; Medication variable dose reconstitution

Graduations (ml) **Needle Size** Other **Needle Size (Other)** 23G x 1 1/4" **Needle Fixation** Detached Yes

Nominal capacity (ml) 3.00 Packaging & Sterility **Assurance**

Yes

Plunger aspiration

Number of pieces 3.00 **RUP** mechanism Gasket lock/plunger break

RUP Type Plunger lock Location RUP activation End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 23G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml) 3.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **RUP Sub-category** Simple RUP

CE marking Yes

Comments Needle at side available Pieces per carton: 2000 or 2400 Graduations: with scale interval of 0.1ml

and 0.5ml increment between graduation lines to benumbered.

PRICE AND SHIPPING

Other needle size options

Shipping volume (m3) 0.0979 Shipping weight (kg) 19.00 Pieces per package 1500 Minimum order 100000.00 Year of base price 2017

Price 1 price on request

Incoterms **FOB**

QUALITY STANDARD

Applicable PQS specification: **Quality Standard** ISO 13485 **Specification Reference**

7886-4 Applicable PQS VP(s):

PRODUCT SITES

Organization name Jiangxi Hongda Medical Equipment Group Ltd

Address 39 South Shengi Road Jinxian county, Nanchang City Jiangxi province China; People's Republic of

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: 3ml LS RUP 23X1 AN Bawal

IMD-PQS Code:E013-125Status:PrequalifiedDate of acceptance:16 May 2019

Appliance type: E013

Product description: 3ml RUP 23X1 **Manufacturer:** Becton Dickinson

Manufacturers Reference: 3ml LS RUP 23X1 AN Bawal

Address: Crtra. Mequinenza (N-211) S/N, 22520, Fraga (Huesca)

Spain

Telephone: +34 974470900

Email: kathy.cooman@bd.com

Website address: http://www.bd.com

Valid until: 31 May 2026

Specifications

Current PQS status:

PRODUCT SPECIFICATIONS -	MAIN		
Intended purpose	Medication variable dose administration	Restrictive use for	None
Graduations (ml)	0.10	Needle Size	Other
Needle Size (Other)	23x1	Needle Fixation	Detached
Nominal capacity (ml)	3.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	3.00	RUP mechanism	Blocking and breaking plunger
RUP Type	Plunger lock	Location RUP activation	End of injection
RUP Needle Fixation	Not Fixed	RUP Needle Sizes	23G x 1" (25 mm)
RUP Nominal Capacity (ml)	3.00	RUP plunger Aspiration	Multiple
RUP Primary Packaging	Blister pack	CE marking	Yes
PRICE AND SHIPPING			
Shipping volume (m3)	0.12	Shipping weight (kg)	13.80
Pieces per package	2400	Minimum order	48000.00
Price 1	price on request	Year of base price	2019
Incoterms	FCA		
QUALITY STANDARD			
Quality Standard	ISO 13485;Other	Quality standard (Other)	ISO 9001
Specification Reference	Applicable PQS specification: Applicable PQS VP(s):		
PRODUCT SITES			
Organization name	Becton Dickinson		
Address	Crtra. Mequinenza (N-211) S/N, United States of America	22520, Fraga (Huesca)	

Valid until:

31 May 2026

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

Prequalified



E013: Injection devices for therapeutic purposes



5ml LS RUP 24X1 AN Bawal Product name:

IMD-PQS Code: F013-126 Prequalified Status: 16 May 2019 Date of acceptance:

Appliance type: E013

Product description: BD Syringe 5ml LS RUP 24X1 AN Bawal

Manufacturer: Becton Dickinson

Manufacturers Reference: 5ml LS RUP 24X1 AN Bawal

Address: Crtra. Mequinenza (N-211) S/N, 22520, Fraga (Huesca)

Spain

None

Telephone: +34 974470900 Email: kathy.cooman@bd.com Website address: http://www.bd.com Valid until: 31 May 2026

Specifications

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Intended purpose Medication fixed dose Restrictive use for administration Graduations (ml) 0.20 **Needle Size** Other

Needle Fixation Detached Needle Size (Other) 24x1 Nominal capacity (ml) 5.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration

Number of pieces 3.00 **RUP** mechanism Locking and breaking plunger

Location RUP activation RUP Type Plunger lock End of injection Not Fixed **RUP Needle Sizes RUP Needle Fixation** 24G x 1" (25 mm)

RUP Nominal Capacity (ml) 5.00 **RUP** plunger Aspiration Multiple Plastic ribbon **CE** marking **RUP Primary Packaging** Yes

PRICE AND SHIPPING

Shipping volume (m3) 0.118 Shipping weight (kg) 11.40 Pieces per package 1600 Minimum order 32000.00 Price 1 Year of base price 2019 price on request

Incoterms **FCA**

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

Applicable PQS VP(s):

PRODUCT SITES

Organization name Becton Dickinson

Address Crtra. Meguinenza (N-211) S/N, 22520, Fraga (Huesca)

United States of America

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: Syringe 10ml LS RUP 21X1 AN Bawal

IMD-PQS Code:E013-127Status:PrequalifiedDate of acceptance:16 May 2019

Appliance type: E013

Product description: BD 10ml RUP 21X1

Manufacturer: Becton Dickinson

Manufacturers Reference: Syringe 10ml LS RUP 21X1 AN Bawal

Address: Crtra. Mequinenza (N-211) S/N, 22520, Fraga (Huesca)

Spain

Telephone: +34 974470900
Email: kathy.cooman@bd.com
Website address: http://www.bd.com
Valid until: 31 May 2026

Specifications

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Intended purpose Medication variable dose Restrictive use for None administration

Graduations (ml)0.20Needle SizeOtherNeedle Size (Other)21X1Needle FixationDetachedNominal capacity (ml)10.00Packaging & SterilityYes

Assurance

Plunger aspiration Yes

Number of pieces 3.00 **RUP mechanism** Locking and breaking plunger

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes21G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml)10.00RUP plunger AspirationMultipleRUP Primary PackagingBlister packCE markingYes

PRICE AND SHIPPING

Other needle size options

Shipping volume (m3)0.1358Shipping weight (kg)13.80Pieces per package1200Minimum order24000.00Price 1price on requestYear of base price2019

Incoterms FCA

QUALITY STANDARD

Quality Standard ISO 13485;Other Quality standard (Other) ISO 9001

Specification Reference Applicable PQS specification:

Yes

Applicable PQS VP(s):

PRODUCT SITES

Organization name Becton Dickinson

Address Crtra. Mequinenza (N-211) S/N, 22520, Fraga (Huesca)

United States of America

Current PQS status:PrequalifiedValid until:31 May 2026





E013: Injection devices for therapeutic purposes

Product name: SHIFA syringe 1ml

IMD-PQS Code: E013-128 Status: Prequalified 20 Oct 2020 Date of acceptance: E013 Appliance type:

Product description: RUP syringe 1ml

Manufacturer: Changzhou Tongda Medical Appliance Co., Ltd

Manufacturers Reference: SHIFA syringe 1ml

Address: Sanhekou Street, Zhenglu Town, Tianning District,

Changzhou, Jiangsu, China. No. 208, Sanhe Road 213115

Changzhou China

+86 51988670522 Telephone: Email: info@tongdamedical.com http://www.tongdachina.com.cn Website address:

Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATIONS	- MAIN

Intended purpose Medication variable dose Restrictive use for None

administration

Graduations (ml) **Needle Size** Other 0.10 **Needle Size (Other)** 26Gx5/8" **Needle Fixation** Detached Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces 3.00 **RUP** mechanism locked & broken pluger **RUP Type** Plunger lock **Location RUP activation** End of injection **RUP Needle Fixation** Not Fixed **RUP Needle Sizes** 26G x 3/8" (10 mm)

RUP Nominal Capacity (ml) 1.00 **RUP** plunger Aspiration Multiple **RUP Primary Packaging** Blister pack **CE** marking Yes

Comments Needle at side available Pieces per carton:2000 or 2400

PRICE AND SHIPPING

Shipping volume (m3) 0.090447 Shipping weight (kg) 12.78 200000.00 Pieces per package 2000 Minimum order 2020 Price 1 price on request Year of base price

Incoterms **FOB**

QUALITY STANDARD

Applicable PQS specification: **Quality Standard** ISO 13485 **Specification Reference**

ISO 7886-4Applicable PQS

VP(s): ISO 7886-4

PRODUCT SITES

Organization name Changzhou Tongda Medical Appliance Co., Ltd

Address Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. No. 208, Sanhe

Road 213115 Changzhou

China

Current PQS status: Prequalified Valid until: 31 May 2026





E013: Injection devices for therapeutic purposes

Product name: SHIFA syringe 3ml

IMD-PQS Code:E013-129Status:PrequalifiedDate of acceptance:20 Oct 2020Appliance type:E013

Product description: RUP syringe 3ml

Manufacturer: Changzhou Tongda Medical Appliance Co., Ltd

Manufacturers Reference: SHIFA syringe 3ml

Address: Sanhekou Street, Zhenglu Town, Tianning District,

Changzhou, Jiangsu, China. No. 208, Sanhe Road 213115

Changzhou China

Telephone: +86 51988670522

Email: info@tongdamedical.com

Website address: http://www.tongdachina.com.cn

Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATIONS - I	MAIN

Intended purpose Medication variable dose Restrictive use for None

administration

Yes

Graduations (ml)0.10Needle SizeOtherNeedle Size (Other)24Gx1"Needle FixationDetachedNominal capacity (ml)3.00Packaging & SterilityYes

Assurance

Plunger aspiration Yes

Number of pieces 3.00 RUP mechanism locked and broken plunger

RUP TypePlunger lockLocation RUP activationEnd of injectionRUP Needle FixationNot FixedRUP Needle Sizes24G x 1" (25 mm)

RUP Nominal Capacity (ml) 3.00 RUP plunger Aspiration Multiple

RUP Primary Packaging Blister pack RUP Sub-category Simple RUP

CE marking Yes

Comments Needle at side available, Pieces per carton:2000 or 2400

PRICE AND SHIPPING

Other needle size options

Shipping volume (m3)0.090447Shipping weight (kg)12.78Pieces per package2000Minimum order200000.00Price 1price on requestYear of base price2020

Incoterms FOB

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 Changzhou Tongda Medical Appliance Co., Ltd

Address Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. No. 208, Sanhe

Road 213115 Changzhou

China

Current PQS status: Prequalified Valid until: 31 May 2026





E013: Injection devices for therapeutic purposes

Product name: SHIFA syringe 5ml

IMD-PQS Code:E013-130Status:PrequalifiedDate of acceptance:20 Oct 2020Appliance type:E013

Product description: RUP syringe 5ml

Manufacturer: Changzhou Tongda Medical Appliance Co., Ltd

Manufacturers Reference: SHIFA syringe 5ml

Address: Sanhekou Street, Zhenglu Town, Tianning District,

Changzhou, Jiangsu, China. No. 208, Sanhe Road 213115

Changzhou China

Telephone: +86 51988670522

Email: info@tongdamedical.com

Website address: http://www.tongdachina.com.cn

Valid until: 31 May 2026

Specifications

Organization name

Current PQS status:

Address

PRODUCT SPECIFICATIONS	- MAIN		
Intended purpose	Medication variable dose administration	Restrictive use for	None
Graduations (ml)	0.20	Needle Size	Other
Needle Size (Other)	23G x 1"	Needle Fixation	Detached
Nominal capacity (ml)	5.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	3.00	RUP mechanism	locked and broken plunger
RUP Type	Plunger lock	Location RUP activation	End of injection
RUP Needle Fixation	Not Fixed	RUP Needle Sizes	24G x 1" (25 mm)
RUP Nominal Capacity (ml)	5.00	RUP plunger Aspiration	Multiple
RUP Primary Packaging	Blister pack	CE marking	Yes
Comments	Needle at side available Piec	es per carton:1600 or 2000	
PRICE AND SHIPPING			
Shipping volume (m3)	0.10212	Shipping weight (kg)	13.70
Pieces per package	1600	Minimum order	200000.00
Price 1	price on request	Year of base price	2020
Incoterms	FOB		
QUALITY STANDARD			
Quality Standard	ISO 13485	Specification Reference	Applicable PQS specification: ISO 7886-4 Applicable PQS VP(s): ISO 7886-4

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

Road 213115 Changzhou

China

Prequalified

Changzhou Tongda Medical Appliance Co., Ltd

Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. No. 208, Sanhe

31 May 2026

Valid until:





E013: Injection devices for therapeutic purposes

Product name: SHIFA syringe 10ml

IMD-PQS Code:E013-131Status:PrequalifiedDate of acceptance:20 Oct 2020Appliance type:E013

Product description: RUP syringe 10ml

Manufacturer: Changzhou Tongda Medical Appliance Co., Ltd

Manufacturers Reference: SHIFA syringe 10ml

Address: Sanhekou Street, Zhenglu Town, Tianning District,

Changzhou, Jiangsu, China. No. 208, Sanhe Road 213115

Changzhou China

Telephone: +86 51988670522
Email: info@tongdamedical.com
Website address: http://www.tongdachina.com.cn

Valid until: 31 May 2026

Specifications

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Intended purpose Medication fixed dose Restrictive use for None

administration; Medication variable dose administration

Graduations (ml)0.50Needle SizeOtherNeedle Size (Other)22Gx1 1/4"Needle FixationDetached

Nominal capacity (ml) 10.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration Yes

Number of pieces3.00RUP mechanismlocked and broken plunger

 RUP Type
 Plunger lock
 Location RUP activation
 End of injection

 RUP Needle Fixation
 Not Fixed
 RUP Needle Sizes
 22G x 1 1/4" (30 mm)

RUP Nominal Capacity (ml)10.00RUP plunger AspirationMultipleRUP Primary PackagingBlister packCE markingYes

Comments Needle at side available Pieces per carton:1600 or 1200

PRICE AND SHIPPING

Shipping volume (m3)0.139776Shipping weight (kg)18.94Pieces per package1600Minimum order200000.00Price 1price on requestYear of base price2020

Incoterms FOB

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 Changzhou Tongda Medical Appliance Co., Ltd

Address Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. No. 208, Sanhe

Road 213115 Changzhou

China

Current PQS status: Prequalified Valid until: 31 May 2026



E013: Injection devices for therapeutic purposes



Product name: 3mL RUP
IMD-PQS Code: E013-133
Status: Prequalified
Date of acceptance: 24 Dec 2021
Appliance type: E013
Product description: 3mL RUP

Manufacturer: Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: 3mL RUP

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China

China

Telephone: +86 (510)3777555

Email: mike@chinasyringe.com

Website address: http://www.chinasyringe.com

Valid until: 31 May 2025

Specifications

PRODUCT SPECIFICATIONS	- MAIN		
Intended purpose	Medication variable dose administration	Restrictive use for	None
Graduations (ml)	0.20	Needle Size	Other
Needle Size (Other)	24Gx1"	Needle Fixation	Detached
Nominal capacity (ml)	3.00	Packaging & Sterility Assurance	Yes
Other needle size options	Yes	Plunger aspiration	Yes
Number of pieces	3.00	RUP Type	Other
Location RUP activation	End of injection	RUP Needle Fixation	Not Fixed
RUP Needle Sizes	24G x 1" (25 mm)	RUP Nominal Capacity (ml)	3.00
RUP plunger Aspiration	Multiple	RUP Primary Packaging	Blister pack
CE marking	Yes		
PRICE AND SHIPPING			
Shipping volume (m3)	0.12	Shipping weight (kg)	12.00
Pieces per package	2400	Minimum order	200000.00
Price 1	Price available on request	Year of base price	2021
QUALITY STANDARD			
Quality Standard	ISO 13485	Specification Reference	Applicable PQS specification: ISO 7886/4 Applicable PQS VP(s):
PRODUCT SITES			
Organization name	Wuxi Yushou Medical Applian	ices Co., Ltd	
Address		an District Wuxi city Jiangsu Provin	ce China
Current PQS status:	Prequalified	Valid until:	31 May 2025





E013: Injection devices for therapeutic purposes

IMD-PQS Code:E013-134Status:SuspendedDate of acceptance:01 Jul 2022Appliance type:E013

Specifications

Current PQS status: Suspended Valid until:



E013: Injection devices for therapeutic purposes



Hongda 1mL RUP syringe Product name:

IMD-PQS Code: E013-135 Prequalified Status: Date of acceptance: 15 Sep 2023

E013 Appliance type:

Product description: 1mL RUP syringe

Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd

Manufacturers Reference: Hongda 1mL RUP syringe

Address: 39 South Shengi Road Jinxian county, Nanchang City

Jiangxi province China; People's Republic of

China

Telephone: +86 791 85628828 hongda008@jxhd.cn Email: Website address: http://www.jxhd.cn Valid until: 31 May 2026

Specifications

PRODUCT	SPECIFICATIONS -	MAIN

Intended purpose Medication variable dose Restrictive use for Insulin administration, Tuberculin administration

administration, Fixed dose 1mL

Needle Size Graduations (ml) 0.02 Other Needle Size (Other) 22GX1mm **Needle Fixation** Fixed Nominal capacity (ml) 1.00 Packaging & Sterility Yes

Assurance

Other needle size options Yes Plunger aspiration

Number of pieces 3.00 **RUP** mechanism gasket and plunger is Locked

RUP Type Plunger lock **Location RUP activation** End of injection

RUP Needle Sizes 22G x 1" (25 mm) **RUP Nominal Capacity (ml)** 1.00 **RUP Primary Packaging** Paper blister pack **CE** marking Yes

Comments Pieces per carton: other quantities per carton available Plunger aspiration: Single

PRICE AND SHIPPING

Shipping volume (m3) 0.097954 Shipping weight (kg) 19.00 Pieces per package 1500 Minimum order 100000.00 Price 1 1000units:3.3\$ Price 2 5000units:3.2\$

10000units:3.1\$ Price 3 Year of base price 2023

QUALITY STANDARD

Quality Standard ISO 13485

PRODUCT SITES

Organization name Jiangxi Hongda Medical Equipment Group Ltd

Address 39 South Shengi Road Jinxian county, Nanchang City Jiangxi province China; People's Republic of

China

Current PQS status: Valid until: 31 May 2026 Prequalified



E013: Injection devices for therapeutic purposes



Product name: Yushou®

IMD-PQS Code: E013-136

Status: Prequalified

Date of acceptance: 15 Jan 2024

Product description: 5mL Syringe with re-use prevention feature **Manufacturer:** Wuxi Yushou Medical Appliances Co., Ltd

Manufacturers Reference: Yushou® Country of Manufacture: China

Address: No.115 Nongxinhe Road Xishan District Wuxi city Jiangsu

Province China

China

Telephone: +86 (510)3777555

Email: mike@chinasyringe.com

Website address: http://www.chinasyringe.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATIONS - MAIN										
Vaccine capacity (mL)	5.00	Graduations (ml)	0.20							
Needle Size	Other	Needle Size (Other)	23Gx25mm							
Needle Fixation	Detached	Syringe material(s)	Polypropylene							
Other needle size options	Yes	Number of pieces	2000.00							
RUP Type	Other	Location RUP activation	End of injection							
RUP ISO Type	Type 1A	RUP Primary Packaging	Paper blister pack							
PRICE AND SHIPPING										
Shipping volume (m3)	0.135	Shipping weight (kg)	15.00							
Units per package	3.00	Pieces per package	2000							
Minimum order	200000.00	Price 1	POA							
Year of base price	2023	Incoterms	FOB							
QUALITY STANDARD										
Quality Standard		ISO 13485								
Current PQS status:	Prequalified	Valid until:	31 May 2026							



E013: Injection devices for therapeutic purposes



Product name: KOJAK SELINGE 5ml

IMD-PQS Code:E013-137Status:PrequalifiedDate of acceptance:05 Jun 2025Product description:RUP Syringe 5ml

Manufacturer: Hindustan Syringes & Medical Devices Ltd.

Manufacturers Reference: KOJAK SELINGE 5ml

Country of Manufacture: India

Address: 174, Sector - 25, Ballabgarh - 121 004 (Haryana) India

India

Telephone: +91 129-4289000

Email: hmduk@hmdhealthcare.com

Website address: www.hmdhealthcare.com

Valid until: 31 May 2026

Specifications

PRODUCT SPECIFICATION	S - MAIN		
Vaccine capacity (mL)	5.00	Graduations (ml)	0.20
Needle Size	Other	Needle Size (Other)	21 GX 11?2" (0.80 X 38 mm)
Needle Fixation	Fixed	Other needle size options	Yes
Number of components	3	RUP mechanism	Locked / Broken Plunger
RUP Type	Other	Location RUP activation	End of injection
RUP ISO Type	Type I B	RUP Primary Packaging	Paper blister pack
CE marking	Yes		
Comments	MDSAP		
PRICE AND SHIPPING			
Shipping volume (m3)	0.0726	Shipping weight (kg)	11.80
Pieces per package	1200	Minimum order	12000.00
Price 1	Over 1 million - USD 4.55/100 Pcs	Price 2	Over 10 millions - USD 4.30/100 Pcs
Price 3	Over 50 millions - USD 4.05/100 Pcs	Year of base price	2025
QUALITY STANDARD			
Quality Standard	ISO 13485;Other	Quality standard (Other)	ISO 9001:2015
Current PQS status:	Prequalified	Valid until:	31 May 2026