

HIELUX

ADVISORY

SUPPLIER INTELLIGENCE REPORT

Syringes & Needles

Asia-Sourced · NL · BE · Rotterdam Hub

EVALUATED 6 Manufacturers	PRESENTED 4 Selected	DELIVERED 7 Business Days
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JUNE 26, 2026

HIELUX ADVISORY · SINGAPORE

DATE June 26, 2026	FREIGHT VALIDITY 14 days from issue
CLASSIFICATION Client-use only	DISTRIBUTION Not for redistribution

Executive Summary

Three findings. One path forward.

RECOMMENDATION	EST. ANNUAL SAVING	ONE OPEN ITEM
Kangyou Medical \$0.0183/unit landed · CE MDR to 2030	\$56K–\$108K vs current market	INI — full MDR cert pending

FINDING 01 — REGULATORY

Kangyou holds CE MDR valid until March 2030 — the strongest certification standing in this report. Combined with the lowest landed cost for standard disposables, it is the primary recommendation for this profile.

FINDING 02 — SPECIALISATION

Yesomed (subsidiary of Shenzhen-listed Suzhou Tianhua, code 300390) is the only supplier in this report that makes safety and auto-disable syringes with full CE MDR and ISO 13485 standing, backed by WHO PQS for auto-disable and a globally audited quality system. For EU safety-syringe and auto-disable lines, no other supplier in this report qualifies.

FINDING 03 — ENTRY POINT

INI Medical offers the lowest MOQ (100,000 units) and the broadest product range, at the second-lowest standard syringe pricing in this report — behind Kangyou. Suitable for a trial order. CE MDR transition was approved May 2024; we confirmed the current certificate status directly with the manufacturer, and the supporting documentation is provided with this report.

PRIMARY RISK

INI Medical's MDR transition status is the only unresolved regulatory question in this report. Every other supplier's certification was verified as current against public records. We confirmed its current status directly with the manufacturer; the full MDR certificate is pending issuance and its documentation accompanies this report.

RECOMMENDED STRATEGY FOR THIS PROFILE

PRIMARY
Kangyou — standard disposables, MDR 2030, lowest landed cost
SAFETY LINES
Yesomed — safety & auto-disable syringes, WHO PQS, CE MDR
TRIAL / ENTRY
INI Medical — low MOQ pilot, pending full MDR cert
NEEDLES / BACKUP
Qiaosend — needle sourcing, backup supply, export-only structure

Client Profile

Who this report was built for

COMPANY	REDACTED
LOCATION	Rotterdam, Netherlands
CHANNEL	Hospital group procurement — NL & BE
PRODUCTS	Single-use syringes, safety needles, insulin syringes
ANNUAL VOLUME	~2.5 million units across SKUs
CURRENT SOURCING	REDACTED

KEY REQUIREMENTS

CE MDR-compliant manufacturers · ISO 13485 audited by recognised body · EO sterilisation with ISO 11135 validation documentation available · Minimum 2 qualified backup suppliers · FOB pricing with CIF Rotterdam calculation including EU ETS

Verification Methodology

What was verified. What was not.

Every claim in this report is sourced. Where verification was not possible or not performed, that is stated explicitly. A report that tells you only what it found is less valuable than one that also tells you what it could not confirm.

Hielux Advisory holds no commercial relationship with any manufacturer in this report. No referral fee, commission, or compensation of any kind was received or solicited. Every assessment reflects independent evaluation against this client's profile only.

VERIFIED

DIRECT SUPPLIER ENGAGEMENT

Each shortlisted supplier maintains a named account contact assigned to Hielux’s category inquiries. Pricing, MOQ, lead times, payment terms, and certification documentation were obtained directly through these contacts via written correspondence and video calls during the evaluation period. No supplier was informed of this report or its intended recipient in advance.

CERTIFICATION CROSS-REFERENCE

CE MDR, FDA (K053519), ISO 13485, and WHO PQS (E008) verified against issuing body records and WHO PQS public database. All further national registrations were confirmed via manufacturer documentation and public registries.

PARENT COMPANY VERIFICATION

Yesomed confirmed as wholly-owned subsidiary of Suzhou Tianhua Super Clean Technology Co., Ltd. (Shenzhen Stock Exchange: 300390). Registered capital RMB 60 million confirmed via public filings.

FREIGHT AND LANDED COST

Ocean freight rates were sourced from the Drewry World Container Index (week of June 25, 2026). EU ETS surcharges were cross-referenced against carrier market rates published by Searoutes and CMA CGM (2026, full ETS phase-in basis).

DOCUMENTATION OBTAINED & INCLUDED

Original certificates, current scope documents, declarations, and current compliance status were obtained directly from each manufacturer, verified against issuing-body and public records, and are included with this report. Hielux re-verifies on renewal or scope change.

RECOMMENDED BEFORE LARGE-VOLUME COMMITMENT

PHYSICAL FACTORY AUDIT

No on-site inspection was conducted. Physical GMP audit should be commissioned independently before large-volume commitment. Recommended for orders above USD 50,000.

EO STERILISATION VALIDATION RECORDS

EO sterilisation was confirmed as the method used. The ISO 11135 validation file — sterilisation cycle validation, bioburden data, sterility assurance level records — is collected from the manufacturer during sample qualification, which Hielux coordinates.

PRODUCTION BATCH QUALITY

Sample quality evaluated for Yesomed only. Pre-production sample evaluation recommended for all other suppliers before first commercial order.

Evaluation Process

How we arrived at these four.

These manufacturers were not the only ones considered. From a broader pool identified across Asia in this product category, six were shortlisted for detailed evaluation against this profile. Of those six, four met the criteria in full.

6

Evaluated against profile

FULL REVIEW

4

Met criteria in full

PRESENTED BELOW

I

Did not meet criteria

SEE NOT RECOMMENDED

I

Outside scope

EXCLUDED

PROCUREMENT SCORECARD

SUPPLIER	MDR STANDING	REG. RISK	FOB PRICE	MOQ FLEX.	CERT. DEPTH	PRODUCT BREADTH	BEST USE
Yesomed	B+	Low	C	B	A	A	SAFETY / AUTO-DISABLE / WHO PQS
INI Medical	C*	Medium*	A	A	B	A	TRIAL ORDERS / BROAD RANGE
Kangyou	A	Low	A	B	B	B	STANDARD PRIMARY SUPPLIER
Qiaosend	B+	Low	B	A	B	B	NEEDLES / BACKUP SOURCE

* INI Medical MDR transition in progress — current status confirmed directly with the manufacturer; documentation enclosed. A = Strong, B = Adequate, C = Weaker relative to this profile. Reg. Risk reflects certification certainty for EU hospital supply.

Supply Chain Overview

Origin to Rotterdam — four supplier lanes

All four suppliers ship to Rotterdam via established Asia–North Europe container lanes. Transit times and port selection vary by supplier location. Sea freight rates reflect Drewry WCI June 2026.

SUPPLIER	ORIGIN PORT	TRANSIT	DESTINATION
Kangyou Medical PRIMARY · STANDARD SYRINGES	→ Shanghai	→ Cape of Good Hope 35–45 DAYS	→ Rotterdam ECT · MAASVLAKTE
Wuxi Yesomed PRIMARY · SAFETY LINES	→ Shanghai	→ Cape of Good Hope 35–45 DAYS	→ Rotterdam ECT · MAASVLAKTE
INI Medical CONDITIONAL · MDR PENDING	→ Ningbo	→ Cape of Good Hope 35–45 DAYS	→ Rotterdam ECT · MAASVLAKTE
Qiaosend Medical BACKUP · NEEDLES	→ Qingdao	→ Cape of Good Hope 38–48 DAYS	→ Rotterdam ECT · MAASVLAKTE

PRIMARY SUPPLIER LANE

SECONDARY / CONDITIONAL LANE

FREIGHT REFERENCE — SHANGHAI / NINGBO TO ROTTERDAM · JUNE 2026

40HQ OCEAN \$4,392	EU ETS SURCHARGE \$168 / 40HQ
LCL OCEAN \$70 / CBM	SOURCE Drewry WCI

Qingdao to Rotterdam is approximately \$50–80 per 40HQ above Shanghai rates on the same lane due to port positioning. As of June 2026, Cape of Good Hope is the standard routing for Asia–North Europe: Red Sea / Suez transit remains largely suspended after Houthi attacks resumed in early 2026, with carriers (led by CMA CGM) only selectively returning to the Suez lane as conditions allow. Cape routing adds roughly 10–14 days versus the pre-disruption Suez transit. Spot rates sit at peak-season levels (mid-2026 GRIs and PSS in force) and are volatile — confirm routing, transit time, and surcharges with your freight forwarder at booking.

Price Comparison

All four factories, side by side.

Factory-direct FOB pricing for the standard disposable and insulin lines — the products all four suppliers make. The lowest price in each row is highlighted. Specialty lines (auto-disable, safety, needles) sit in each supplier’s own section, since not every factory produces them.

FOB / UNIT · USD	Kangyou	INI Medical	Yesomed	Qiaosend
1 ml	\$0.0145	\$0.0200	\$0.024	\$0.022
3 ml	\$0.0145	\$0.0165	\$0.022	\$0.0225
5 ml	\$0.0153	\$0.0175	\$0.023	\$0.023
10 ml	\$0.022	\$0.0258	\$0.031	\$0.034
20 ml	\$0.0356	\$0.0395	\$0.043	\$0.050
50 ml	\$0.088	\$0.099	—	\$0.125
Insulin 0.5 / 1 ml	\$0.0235	\$0.028	\$0.030	\$0.032

All prices FOB (factory-direct, USD). — = size not offered by that supplier. Kangyou is lowest in every standard size — the basis for its primary recommendation. Delivered cost (CIF Rotterdam) follows on the next page.

Landed Cost

From factory quote to delivered cost.

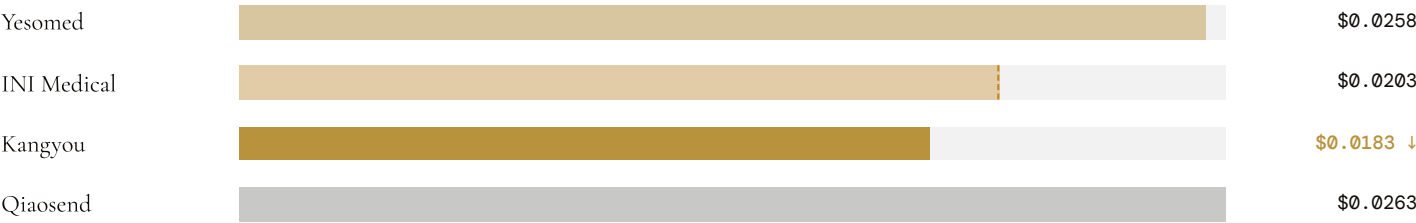
FOB is the factory quote. What you actually pay is the landed cost — FOB plus ocean freight, EU ETS and insurance to CIF Rotterdam. Because all four ship the same China–North Europe lane, the freight add is roughly the same for each (about \$0.0038 per unit at full-container volume) — so the cheapest quote stays the cheapest delivered.

3 ML STANDARD · CIF ROTTERDAM · PER UNIT · JUNE 2026

Supplier	FOB	+ ship · ETS · ins	CIF · full 40HQ	CIF · trial (LCL)
Kangyou	\$0.0145	+\$0.0038	\$0.0183	\$0.0197
INI Medical	\$0.0165	+\$0.0038	\$0.0203	\$0.0229
Yesomed	\$0.022	+\$0.0038	\$0.0258	\$0.0273
Qiaosend	\$0.0225	+\$0.0038	\$0.0263	\$0.0289

Full-container (40HQ) basis · freight \$4,392/40HQ + EU ETS \$168 + insurance 0.3% · June 2026. Trial-order (LCL) cost is higher per unit because small shipments pay more freight per CBM.

LANDED COST PER UNIT · FULL 40HQ · CIF ROTTERDAM



What the numbers say

For standard disposable syringes with full MDR compliance, Kangyou is the primary recommendation. For safety syringes and auto-disable (WHO PQS) lines, Yesomed is the only option in this report. For a low-MOQ trial order, INI Medical — subject to MDR confirmation. For needles and backup supply, Qiaosend. These four are not interchangeable — they serve different parts of a supply chain.

** INI Medical MDR transition approved May 2024 — current status confirmed directly with the manufacturer; documentation provided with this report.*

Savings Analysis

What this means in dollars.

WHAT THIS ASSUMES

Volume and SKU mix follow the client profile on page 03. Current spend is estimated against aggregate third-party EU import benchmarks for Chinese-manufactured disposable medical devices. New spend uses verified factory-direct pricing from the four shortlisted suppliers. A tailored client report uses the buyer's actual SKU breakdown and current supplier pricing for precise calculation.

CURRENT ANNUAL SPEND

\$108K – \$160K

Estimated · market benchmark midpoints

NEW ANNUAL SPEND

\$52,000

Verified · cost-optimized allocation

SAVED ANNUALLY

\$56,000 – \$108,000

AGAINST REPORT COST OF \$1,500 · PAYBACK WITHIN FIRST ORDER CYCLE

BREAKDOWN BY SKU CATEGORY

SKU CATEGORY	VOLUME	MARKET RANGE	RECOMMENDED	Y1 SAVINGS
3ml standard syringe	1,200,000	\$0.040 – \$0.060	Kangyou · \$0.0183	\$26K – \$50K
5ml standard syringe	400,000	\$0.045 – \$0.065	Kangyou · \$0.0193	\$10K – \$18K
10ml standard syringe	200,000	\$0.060 – \$0.085	Kangyou · \$0.0275	\$6K – \$11K
1ml insulin syringe	300,000	\$0.050 – \$0.075	Kangyou · \$0.0299	\$6K – \$14K
Safety syringe 3ml	200,000	\$0.060 – \$0.090	Yesomed · \$0.0269	\$7K – \$13K
Standard hypodermic needle	200,000	\$0.015 – \$0.025	Yesomed · \$0.0125	\$1K – \$2K

Market benchmark derived from US Census Bureau and Eurostat HS 9018.31 import data (2023), adjusted to reflect third-party distributor pricing — excludes pharma intercompany transfers and private-label offshore IP structures. Savings are gross of switching costs, transition timelines, and working capital adjustment, and are rounded to the nearest \$1,000. Allocation strategy follows.

Allocation Strategy

Two ways to deploy these findings.

The four shortlisted suppliers can be deployed under two distinct procurement strategies. Each optimizes for a different priority. The right choice depends on the buyer's operational maturity, supply chain risk tolerance, and forward sourcing strategy.

STRATEGY A Cost-optimized SKU-by-SKU matching to lowest-cost qualified supplier. Maximum landed-cost savings. ALLOCATION Standard disposables + insulin · Kangyou Safety syringes + needles · Yesomed Broad-range / low-MOQ · INI Medical (post-MDR) Backup / needle alternative · Qiaosend ESTIMATED ANNUAL ~\$52,000 <i>\$56K – \$108K saved vs current market</i> TRADE-OFFS Four supplier relationships to manage · separate QA processes · separate EUAR coordination per origin · best per-unit pricing on every SKU	STRATEGY B Operationally-simple Concentrated primary supplier with one backup. Slight cost premium for operational simplicity and supply chain priority. ALLOCATION Primary (~70%) · Yesomed covers every SKU type — standard, safety, auto-disable and insulin — under one CE MDR + ISO 13485 + WHO PQS cert stack Backup (~30%) · Kangyou cost backstop on standard disposables; MDR-confirmed ESTIMATED ANNUAL ~\$64,000 <i>\$44K – \$96K saved vs current market</i> TRADE-OFFS Two supplier relationships · one primary supplier covers every SKU type under a single CE MDR / ISO 13485 cert stack · supply chain priority during constraints · ~\$12K higher annual cost
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WHICH STRATEGY FITS Strategy A suits buyers with mature procurement infrastructure who can manage four supplier relationships and want maximum per-unit savings. Hospital procurement groups with established EU MDR processes typically operate here. Strategy B suits buyers with leaner procurement teams who prefer to consolidate every SKU type with one qualified primary supplier, or supply chains where stockout risk carries higher commercial cost than the ~\$12K per-year premium. Distributors who value a single primary relationship over per-SKU price optimisation typically operate here.
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SUPPLIER 01 OF 04

Kangyou Medical

Changzhou, Jiangsu Province, China · FOB Shanghai · en.kym.cn

Best fit: Standard disposable syringes · Primary EU MDR-compliant supplier · Lowest landed cost

CE MDR · Valid March 2030 ISO 13485

EU Authorised Representative: Shanghai International Holding Corp. GmbH, Europe. Total facility 66,700m², Class 100,000 cleanroom 15,000m². Product range includes CE MDR-certified surgical staplers (anorectal, linear, tube, skin) — quality management system tested across more complex device categories than syringe-only factories. Rated AAA credit grade by Changzhou authorities.

INSULIN SYRINGES		
SIZE	FOB / UNIT	MOQ
0.5ml / 1ml	\$0.0235	200,000

SALES CONTACT — SHIRLEY

PROVIDED UPON ENGAGEMENT

FOB PORT — SHANGHAI

SUPPLIER 01 · ASSESSMENT

Kangyou Medical

Changzhou, Jiangsu · FOB Shanghai

PROFILE

Kangyou carries the strongest regulatory standing in this report — CE MDR valid until March 2030, EUAR held by Shanghai International Holding Corp. GmbH in Europe. That is a fully structured EU compliance chain. Their manufacturing scope extends to CE MDR-certified surgical staplers alongside syringes, infusion sets, and blood transfusion sets. A factory that produces certified surgical staplers operates a quality management system tested against more complex device categories than syringe-only manufacturers. Rated Changzhou AAA credit-grade enterprise. Communication responsiveness was consistent throughout evaluation. Direct supplier engagement conducted independently.

THE ECONOMIC CASE

Lowest FOB pricing for standard disposable syringes in this report — \$0.0145/unit on 3ml FOB Shanghai. Strongest MDR standing. At full 40HQ volume, landed cost to Rotterdam is \$0.0183/unit. For a distributor whose primary requirement is standard disposable syringes for EU hospital procurement, this is the primary recommendation in this report. Pricing at MOQ stage is fixed. Volume contract terms — including price adjustment, priority allocation, and extended payment flexibility — are available through a documented commitment with defined quantity and timeline.

FINANCIAL STANDING NOTE

Kangyou has been rated Changzhou AAA credit-grade enterprise and holds the "Jiangsu Medical Device Manufacturing Enterprises Integrity Unit" designation. For buyers conducting supplier financial due diligence, these are verifiable public designations. For orders above USD 50,000, a full financial due diligence check is recommended independently of this report.

SALES CONTACT — SHIRLEY

PROVIDED UPON ENGAGEMENT

FOB PORT — SHANGHAI

SUPPLIER 02 OF 04

Wuxi Yesomed

Wuxi, Jiangsu Province, China · FOB Shanghai · en.chinasyringe.com

Best fit: Safety & auto-disable syringes · WHO PQS · deepest certification stack

- CE MDR
- ISO 13485
- FDA · K053519 · Since 2006
- WHO PQS · E008 · AD syringe
- + registered in 100+ markets

Wholly-owned subsidiary of Suzhou Tianhua Super Clean Technology Co., Ltd. (Shenzhen Stock Exchange: 300390). Registered capital RMB 60 million. Factory 50,000m², clean workshop 11,000m². 24 domestic patents (11 invention, 13 utility model) + patents in USA, Europe, India, Indonesia, PCT. Products exported to approximately 100 countries.

MOQ – SYRINGES 200,000 units	MOQ – NEEDLES 1,000,000 units	LEAD TIME 30 days from deposit
PAYMENT TERMS 30% deposit · 70% before shipment	FDA CLEARANCE K053519 · Safety syringe · since 2006	WHO PQS Auto-disable syringe only · PQS E008

ANNUAL PRODUCTION CAPACITY

SELF-DESTRUCTING 600 million units	SAFETY SYRINGES 500 million units	STANDARD DISPOSABLE 400 million units
INSULIN SYRINGES 200 million units	HIGH-PRESSURE SYRINGES 4 million units	SURGICAL INSTRUMENTS 2 million sets

Wuxi Yesomed · Pricing

FOB Shanghai · All prices USD · EO sterilised · Latex-free · Medical-grade PP

AUTO-DISABLE (AD) · WHO PQS E008 CERTIFIED			
SIZE	FOB/UNIT	MOQ	CARTON
0.05ml	\$0.025	200,000	3,000
0.5ml	\$0.020	200,000	3,000

RE-USE PREVENTION (RUP)			
SIZE	FOB/UNIT	MOQ	CARTON
1ml	\$0.028	200,000	3,000
3ml	\$0.0205	200,000	2,400
5ml	\$0.0215	200,000	2,000
10ml	\$0.033	200,000	1,600

INSULIN SYRINGES · MDR · ISO 13485			
SIZE	FOB/UNIT	SIZE	FOB/UNIT
0.3ml	\$0.032	1ml	\$0.030
0.5ml	\$0.030	—	—

NEEDLES · FDA · MDR · ISO 13485			
PRODUCT	GAUGE	FOB/UNIT	MOQ
Safety needle	18G-30G	\$0.022	1,000,000
Standard needle	18G-30G	\$0.007	1,000,000
Insulin pen needle	29G-32G	\$0.019	200,000
Safety and standard needle MOQ is 1,000,000 units. Insulin pen needle MOQ is 200,000 units.			

All prices FOB Shanghai. WHO PQS covers auto-disable syringe (E008) only — does not extend to needles or standard disposable lines. High-pressure syringes (imaging use) available — request pricing separately. 2-Part Luer Slip available on request at marginally lower pricing.

SUPPLIER 02 · ASSESSMENT

Wuxi Yesomed

Wuxi, Jiangsu · FOB Shanghai · Subsidiary of Shenzhen-listed Suzhou Tianhua (300390)

PROFILE

Yesomed's legal entity is Wuxi Yushou Medical Appliances Co., Ltd., a wholly-owned subsidiary of Suzhou Tianhua Super Clean Technology — Shenzhen-listed (code 300390) since 2014, which acquired Wuxi Yushou in 2015. That parent structure provides financial stability and audit trail that privately-held factories cannot offer. Initial contact requires persistence. Once established, the relationship is consistent — documentation, samples, and responses arrive without delay. Communication responsiveness remained consistent throughout all document and sample requests during evaluation.

CERTIFICATION DEPTH

Yesomed's regulatory clearances span more markets than any other supplier in this report. FDA clearance K053519 has been current since 2006. WHO PQS E008 covers auto-disable syringes — this certification is specific to that product line only and does not extend to needles or standard disposables. Its globally audited quality system — held by only a small fraction of Chinese manufacturers and certified well beyond the EU baseline — underwrites the CE MDR and ISO 13485 standing that matters for EU supply. For a distributor whose channel requires safety-syringe compliance for EU hospital procurement, no other supplier in this evaluation matches this depth.

WHERE TO USE THEM

Safety syringes — AD, RUP, and safety clip — are this factory's core capability. Their annual safety syringe capacity of 500 million units and 24 domestic patents reflect sustained investment in this specific technology. For standard luer lock at volume, Kangyou delivers a lower landed cost. For safety lines, imaging (high-pressure) syringes, or any line requiring WHO PQS auto-disable certification, Yesomed is the appropriate first call. Volume contract pricing is negotiable through a documented commitment — not at MOQ inquiry stage.

SALES CONTACT
PROVIDED UPON ENGAGEMENT
FOB PORT — SHANGHAI

SUPPLIER 03 OF 04

Zhejiang INI Medical

Wenzhou, Zhejiang Province, China · FOB Ningbo / Shanghai · inimd.com

Best fit: Low-MOQ trial orders · Broad product range including biopsy and aesthetic needles

CE MDR

ISO 13485 · TUV Rheinland Audited

MDR transition – status confirmed with manufacturer

MDR transition approved May 2024. Full MDR certification expected 2026. Current certificate status and number were confirmed directly with the manufacturer; the supporting documentation accompanies this report. MDD certificate expired November 2025 – though under the EU 2023/607 transition, a legacy MDD certificate backed by an MDR application filed by May 2024 is generally deemed valid to 2027–2028, subject to conditions. ISO 13485 audited by TUV Rheinland. 26,000m² facility, 8,000m² Class 100,000 cleanroom. 400+ employees. Annual output RMB 150 million (2024).

SAFETY SYRINGES			
SIZE	FOB/UNIT	SIZE	FOB/UNIT
1ml	\$0.027	5ml	\$0.028
3ml	\$0.027	10ml	\$0.041

INSULIN SYRINGES & PEN NEEDLES · MOQ 100,000	
PRODUCT	FOB/UNIT
Insulin syringe 0.5ml / 1ml (U-40 / U-100)	\$0.028
Insulin pen needle 29G–32G (4/5/6mm)	\$0.015

SALES CONTACT – ELENA
PROVIDED UPON ENGAGEMENT
PORT – NINGBO / SHANGHAI

SUPPLIER 03 · ASSESSMENT

Zhejiang INI Medical

Wenzhou, Zhejiang · FOB Ningbo / Shanghai

PROFILE

INI Medical's widest differentiator is product breadth. Alongside standard and safety syringes, their catalogue includes Tru-Cut biopsy needles, aesthetic medicine cannulas (sealed-circle side-hole design for filler injection procedures), insulin pen needles in three lengths (4/5/6mm, 31G–32G), vaccine syringes, and needle cannulas. A distributor whose product mix extends beyond basic injection devices can consolidate more sourcing here than with any other supplier in this evaluation. ISO 13485 is audited by TUV Rheinland — an internationally recognised body with independent audit credibility. 20+ quality tests per batch with 100% needle sharpness and patency inspection. Communication responsiveness was consistent throughout evaluation.

MDR STATUS — CONDITIONAL RECOMMENDATION

MDR STATUS — CONFIRMED DIRECTLY WITH THE MANUFACTURER

INI Medical's CE MDR transition was approved May 2024. Full MDR certification is expected in 2026. Their MDD certificate expired November 2025 — though under the EU 2023/607 transitional provisions, a legacy MDD certificate backed by an MDR application filed by May 2024 is generally "deemed valid" through 2027-2028. For Dutch and Belgian hospital tenders where MDR compliance is a contractual requirement, we confirmed the current certificate status directly with the manufacturer before issuing this report, and the supporting documentation is enclosed. Should the certificate be reissued or its scope change after this date, Hielux will obtain the updated document on the client's behalf.

WHERE TO USE THEM

Second-lowest standard syringe pricing in this report (\$0.0165/unit, 3ml FOB — behind Kangyou's \$0.0145) and lowest MOQ at 100,000 units. Once the full MDR certificate issues, INI Medical is suitable as a secondary supplier for standard disposables and a primary source for the specialised needle categories no other supplier in this report covers. Volume contract terms are available with documented commitment — not at first inquiry stage.

EO STERILISATION DOCUMENTATION

EO sterilisation is confirmed across all INI Medical product lines. The ISO 11135 validation documentation — cycle validation reports, bioburden data, and sterility assurance level (SAL) records — is collected from the manufacturer during sample qualification, which Hielux coordinates. This documentation is standard for EU hospital procurement and is prepared ahead of tender submission.

SALES CONTACT — ELENA
PROVIDED UPON ENGAGEMENT
PORT — NINGBO / SHANGHAI

SUPPLIER 04 OF 04

Qiaosend Medical

Zibo, Shandong Province, China · FOB Qingdao · qiaosend.com.cn

Best fit: Needle sourcing · Backup supply line · Low-MOQ entry · Export-specialist structure

CE MDR · Valid July 2029

ISO 13485

Sino-US joint venture. Subsidiary of Shandong Qiaopai Group Co., Ltd. Registered capital USD 3.5 million. EU Authorised Representative: MedNet EC-REP GmbH. EO sterilisation. Export-only operation — domestic China market handled separately by parent Qiaopai entity. Established 2006. Cleanroom 10,000m². Supplies 30+ countries across Europe, Middle East, South America, Southeast Asia, Africa.

NEEDLES — MOST COMPETITIVE PRICING IN THIS REPORT		
PRODUCT	FOB / UNIT	MOQ
Hypodermic needle 18G	\$0.009	100,000
Hypodermic needle 19G–27G	\$0.0085	100,000
Insulin syringe 0.5ml / 1ml	\$0.032	200,000

ASSESSMENT

Qiaosend's structure is the distinguishing factor. Built as an export-only joint venture from inception, their compliance infrastructure was not adapted from a domestic manufacturing model — it was designed for international supply from the start. CE MDR valid July 2029, EUAR with MedNet EC-REP GmbH. Standard syringe pricing is higher than Kangyou and INI Medical for comparable SKUs, but needle pricing is the most competitive in this report. The appropriate positioning for this profile is secondary supplier for needles and backup supply line for syringes. MOQ of 100,000 units provides accessibility for trial orders.

SALES CONTACT — MERLIN

PROVIDED UPON ENGAGEMENT

FOB PORT — QINGDAO

Evaluated · Not Recommended

Guangdong Haiou

Guangdong Haiou Medical Apparatus Co., Ltd. · Puning City, Guangdong

FOB Shantou · haiou.net.cn

DID NOT MEET PROFILE CRITERIA

- O1

MOQ MISMATCH

500,000 unit minimum — 2.5× above profile requirement

For a first order with an unverified supplier, this cash commitment is disproportionate to the profile requirements and appropriate risk tolerance at initial engagement stage.
- O2

NO DIRECT RELATIONSHIP

Evaluation based on price sheet only — no engagement conducted

No direct communication, no named contact engagement, no sample evaluation. Hielux does not recommend suppliers where direct independent engagement has not occurred prior to the report.
- O3

PORT LIMITATION

FOB Shantou — limited direct service to Rotterdam

Fewer direct vessel services to Rotterdam than Shanghai, Ningbo, or Qingdao. Transit reliability and carrier selection are materially more limited on this lane.

MOQ 500,000 units	FOB PORT Shantou	CERTIFICATIONS HELD FDA · WHO PQS · CE · ISO 13485
RELATIONSHIP STATUS Price sheet only · no direct contact		

CONDITIONS FOR RECONSIDERATION

Haiou's certification stack — FDA, WHO PQS, CE, ISO 13485 — is solid. If direct supplier engagement is established, samples are evaluated, and order volume justifies 500,000 units, Haiou becomes viable, particularly for safety syringe lines where their pricing is competitive at scale.

First Order Reference

Typical first order timeline — Asia to Rotterdam

Timelines are indicative only. Actual schedules vary by supplier responsiveness, sample evaluation duration, and production scheduling.

DAY 1-3	Initial contact. NDA if required. Confirm product specifications and request proforma invoice.
DAY 4-10	Sample dispatch from factory. Courier charges paid by buyer. One sample order standard — product typically at no cost.
DAY 11-20	Sample evaluation against specification. ISO 11135 sterilisation documentation review. Clinical team sign-off if required.
DAY 21-35	Final quotation. Purchase order issued. Deposit transferred (typically 30%). MOQ pricing is fixed at this stage.
DAY 36-65	Production. 30 days standard lead time from deposit receipt. Balance payment (70%) due before shipment.
DAY 66-110	Sea freight — Shanghai/Ningbo to Rotterdam via Cape of Good Hope. 35-45 days transit. LCL or FCL by volume.
DAY 111-120	Customs clearance Rotterdam. Import duty, VAT, and EORI requirements are buyer responsibility — verify with customs broker before shipment. Delivery to warehouse.

Next Steps

What to do now — and how Hielux can help.

YOUR IMMEDIATE ACTIONS

01	FIRST · INI MEDICAL	Review the INI Medical CE MDR certificate provided with this report — status confirmed directly with the manufacturer, product scope covering your SKUs. The full MDR certificate is pending issuance; Hielux will deliver it the moment it issues and flag any change before your PO.
02	FIRST · KANGYOU	Request Kangyou samples for your primary SKUs (3ml, 5ml, 10ml luer lock). Specify your product requirements in writing — material spec, packaging, labelling — to receive the correct sample configuration.
03	PARALLEL · YESOMED	If safety syringes are in your product range, initiate Yesomed qualification in parallel. Request AD and RUP samples; the EU MDR and ISO 13485 documentation is already provided with this report.
04	MEDIUM TERM	Designate Qiaosend as backup needle supplier. Confirm needle specifications and request a sample order. This relationship can be maintained at low effort as a qualified backup source.
05	BEFORE FIRST PO	The current CE certificates (with scope confirmation) are provided with this report. Before your first PO, request the proforma invoice from the supplier — and do not transfer the deposit without a signed PI in hand.

FROM HERE, HIELUX CAN MANAGE

- Supplier qualification** — sample coordination and testing against your specs. (Certificates in this report are already verified; Hielux re-checks on renewal or scope change.)
- Volume contract structuring** — defined quantity and timeline to open pricing that doesn't exist at first-order stage.
- Sourcing engagement** — we manage communication, negotiation and order coordination on your behalf.
- Ongoing supply-chain management** — repeat orders, pricing reviews, backup activation and market intelligence.

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Appendix

Incoterms, scope & disclaimer

INCOTERMS REFERENCE

FOB – FREE ON BOARD

Seller delivers goods onto the vessel at origin port. Buyer assumes all costs and risk from that point — ocean freight, insurance, destination charges, import duties. All prices in this report are FOB.

CIF – COST, INSURANCE & FREIGHT

Seller pays ocean freight and insurance to the destination port. Buyer assumes risk once goods are loaded at origin but seller arranges and pays for transit. All landed cost calculations in this report are CIF Rotterdam.

LCL – LESS THAN CONTAINER LOAD

Shipment shares container space with other cargo. Charged per CBM (cubic metre). Used for MOQ-level orders. Higher per-unit freight cost than FCL. Suitable for trial orders and initial qualification shipments.

FCL – FULL CONTAINER LOAD

Entire container dedicated to one shipment. Charged per container. Lower per-unit freight cost. 40HQ (high-cube 40-foot) is the standard container used for medical consumables — approximately 76 CBM usable volume.

EU ETS SURCHARGE

Carrier surcharge for EU Emissions Trading System compliance on voyages involving EU ports. Rate used: \$168 per 40HQ and ~\$25 per LCL shipment — current market rate confirmed by Searoutes and CMA CGM (2026, Asia–North Europe lane — full ETS phase-in). Rates are revised quarterly by carriers. Verify with freight forwarder at booking.

DDP – DELIVERED DUTY PAID

Seller delivers goods to buyer's premises, all costs and duties paid. Not the default terms for suppliers in this report — all pricing is FOB. DDP is available from some suppliers on request and typically adds 8–15% to FOB price on this lane.

SCOPE OF THIS REPORT

CIF ROTTERDAM IS THE BOUNDARY OF THIS REPORT

This report covers supplier evaluation, FOB pricing, and landed cost calculation to CIF Rotterdam. Import duties, customs clearance, EORI registration, VAT, and any post-arrival logistics are the buyer's responsibility and outside the scope of this engagement. Buyers should verify applicable import duties and trade measures with their customs broker before placing orders. Note: the EU's International Procurement Instrument measure on Chinese medical devices (in force since June 2025) can cap Chinese-origin content in EU public-procurement tenders at or above €5 million — material where the supply feeds public hospital tenders.

DISCLAIMER

All pricing, certification status, MOQ, lead time, and freight data was sourced directly from named supplier representatives and verified against available public records at the time of preparation (June 2026). Certifications remain subject to renewal, suspension, or scope change after that date; Hielux re-verifies on renewal. Freight rates reflect live market data at time of publication and are subject to change without notice. Hielux Advisory makes no warranty as to the fitness of any supplier for any specific regulatory, clinical, or commercial purpose, and assumes no liability for decisions made on the basis of this report. Factory audit and legal review are the buyer's responsibility prior to commercial engagement. This report is prepared for the named client only and is not intended for redistribution or resale. Hielux Advisory holds no financial interest in any manufacturer featured in this report.