HIELUX

ADVISORY

SUPPLIER INTELLIGENCE REPORT

Syringes & Needles

Asia-Sourced · NL · BE · Rotterdam Hub

EVALUATED	PRESENTED	TURNAROUND
6 Manufacturers	3 Selected	7–14 Business Days

PREPARED TO A REPRESENTATIVE CLIENT PROFILE

NL Hospital-Channel Distributor

JULY 20, 2026

HIELUX ADVISORY · SINGAPORE

DATA AS OF July 20, 2026	FOB VALIDITY 30 days from issue
CLASSIFICATION Published sample	FREIGHT & CIF Repriced at booking

Executive Summary

Three findings. One path forward.

RECOMMENDATION	EST. ANNUAL SAVING	OPEN ITEMS
Kangyou Medical $0.0187/unit landed · CE MDR to 2030	$61K–$120K vs current market	None — all certs verified current

FINDING 01 — REGULATORY

Kangyou is the primary recommendation for standard disposables: CE MDR valid to March 2030 — the longest of the three presented — and the lowest landed cost.

FINDING 02 — SPECIALISATION

Yesomed (subsidiary of Shenzhen-listed Suzhou Tianhua, 300390) is the only presented supplier making safety and auto-disable syringes with CE MDR and ISO 13485 standing, backed by WHO PQS (E008) for auto-disable. For EU safety-syringe lines it is the only qualified option in this evaluation.

FINDING 03 — EXCLUSIONS

Two of six evaluated suppliers were excluded — one on MOQ and port constraints, one on unresolved CE MDR transition status. Under current EU MDR enforcement, a pending certificate is a supply risk, not a discount opportunity. Both exclusions are documented on the Not Recommended pages.

PRIMARY RISK

No unresolved regulatory questions remain among the three presented suppliers — every certification was verified current against issuing-body records. The remaining gap is physical: no on-site GMP audit has been conducted. Commission one before large-volume commitment.

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

NEEDLES / BACKUP / ENTRY

Qiaosend — needle sourcing, backup supply, low-MOQ entry at 100,000 units

Client Profile — Representative

The profile this sample was built to

COMPANY	Representative profile — mid-size EU distributor
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	Representative — EU wholesale channel, benchmarked at market rates

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.

> 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 the stated 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 July 16, 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 three.

Six manufacturers were shortlisted from a broader Asia-wide pool and evaluated in detail against this profile. Three met the criteria in full; two did not; one fell outside scope.

1	2	3	×	×	—

3 presented
Kangyou · Yesomed · Qiaosend — certifications verified current

2 not recommended
INI — MDR pending · Haiou — MOQ & port

1 outside scope

PROCUREMENT SCORECARD

SUPPLIER	MDR STANDING	REG. RISK	FOB PRICE	MOQ FLEX.	CERT. DEPTH	PRODUCT BREADTH	BEST USE
Yesomed	A	Low	C	B	A	A	SAFETY / AUTO-DISABLE / WHO PQS
Kangyou	A	Low	A	B	B	B	STANDARD PRIMARY SUPPLIER
Qiaosend	A	Low	B	A	B	B	NEEDLES / BACKUP SOURCE

How to read the grades: ***MDR standing*** *scores the documented EU position — certificate standing and compliance chain. All three presented suppliers hold CE MDR verified current — Kangyou dated to March 2030, Qiaosend to July 2029, Yesomed's certificate on file — with complete EU chains: A across the board. Suppliers that could not clear this bar were removed before presentation. Differentiation between the three sits in price, MOQ, certification depth, and product breadth.* ***Reg. Risk*** *asks whether the certification is certain for EU hospital supply — all three pass at Low; the evaluated supplier that did not is on the Not Recommended pages. A = Strong, B = Adequate, C = Weaker relative to this profile.*

COMMERCIAL TERMS AT A GLANCE

SUPPLIER	FOB PORT	STANDARD MOQ	LEAD TIME	PAYMENT
Kangyou	SHANGHAI	200,000 UNITS	30 DAYS FROM DEPOSIT	30% DEPOSIT · 70% BEFORE SHIPMENT
Yesomed	SHANGHAI	200,000 UNITS	30 DAYS FROM DEPOSIT	30% DEPOSIT · 70% BEFORE SHIPMENT
Qiaosend	QINGDAO	100,000 UNITS	30 DAYS FROM DEPOSIT	30% DEPOSIT · 70% BEFORE SHIPMENT

Terms confirmed directly with each supplier during evaluation. Volume terms open with a documented commitment of quantity and timeline — not at first-inquiry stage.

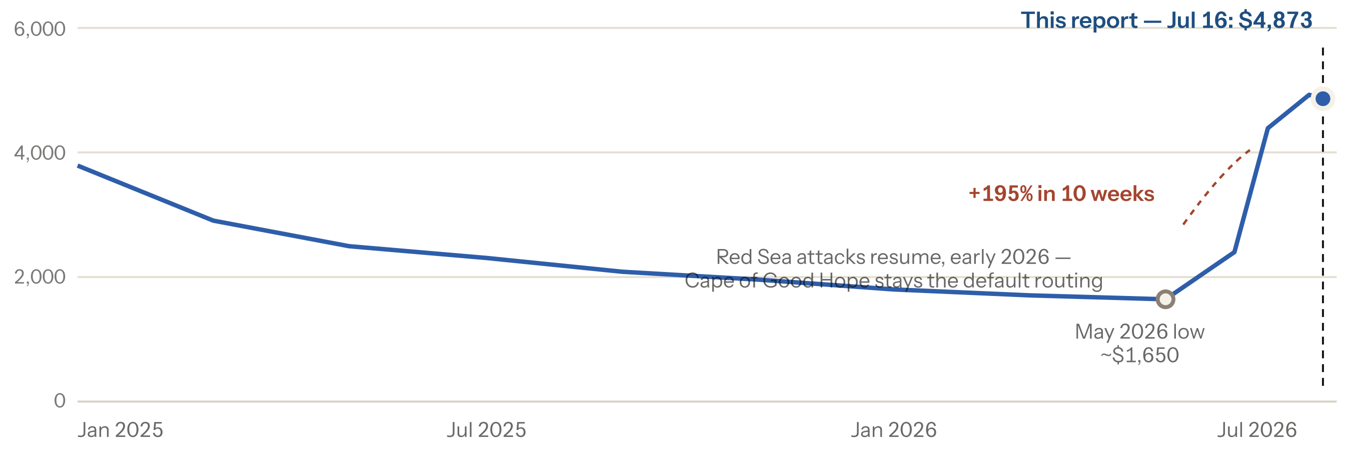
Supply Chain Overview

Where this quote sits in the cycle — and three supplier lanes.

All three suppliers ship Rotterdam on the Asia–North Europe lane. Freight is quoted at the Drewry WCI reading of July 16, 2026 — taken at peak season, which makes the savings in this report conservative.

Freight tripled in ten weeks — this report prices at the peak

Spot rate, Shanghai → Rotterdam, USD per 40ft container



Source: Drewry World Container Index. Weekly readings Jun 25 – Jul 16, 2026 plotted exactly; earlier curve indicative between published anchors.

SUPPLIER LANES · CAPE OF GOOD HOPE ROUTING

SUPPLIER	ORIGIN PORT	TRANSIT	DESTINATION
Kangyou	SHANGHAI	35–45 DAYS	ROTTERDAM · ECT MAASVLAKTE
Yesomed	SHANGHAI	35–45 DAYS	ROTTERDAM · ECT MAASVLAKTE
Qiaosend	QINGDAO	38–48 DAYS	ROTTERDAM · ECT MAASVLAKTE

FREIGHT REFERENCE — SHANGHAI / QINGDAO TO ROTTERDAM · JULY 2026

40HQ OCEAN $4,873	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 July 2026, Cape of Good Hope remains the standard routing for Asia–North Europe: Red Sea / Suez transit is still suspended for most services after Houthi attacks resumed in early 2026, with carriers returning to the Suez lane only selectively — CMA CGM has signalled a fuller return and Maersk has run trial transits as conditions allow. Cape routing adds roughly 10–14 days versus the pre-disruption Suez transit. Spot rates sit at peak-season levels — Shanghai–Rotterdam rose through early July before easing 1% in the week of July 16, with mid-July general rate increases in force — and remain volatile; confirm routing, transit time, and surcharges with your freight forwarder at booking.

Price Comparison

All three factories, side by side.

Factory-direct FOB pricing for the standard disposable and insulin lines — the products all three factories make. The lowest price in each row is highlighted. Specialty lines (auto-disable, safety, needles) sit in each supplier's own section.

FOB / UNIT · USD	Kangyou	Yesomed	Qiaosend
1 ml	**$0.0145**	$0.024	$0.022
3 ml	**$0.0145**	$0.022	$0.0225
5 ml	**$0.0153**	$0.023	$0.023
10 ml	**$0.022**	$0.031	$0.034
20 ml	**$0.0356**	$0.043	$0.050
50 ml	**$0.088**	—	$0.125
Insulin 0.5 / 1 ml	**$0.0235**	$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 pay is the landed cost: FOB plus ocean freight, EU ETS and insurance to CIF Rotterdam. All three ship the same China–North Europe lane, so the freight add is near-identical (about $0.0042 per unit at full-container volume) — the cheapest quote stays the cheapest delivered.

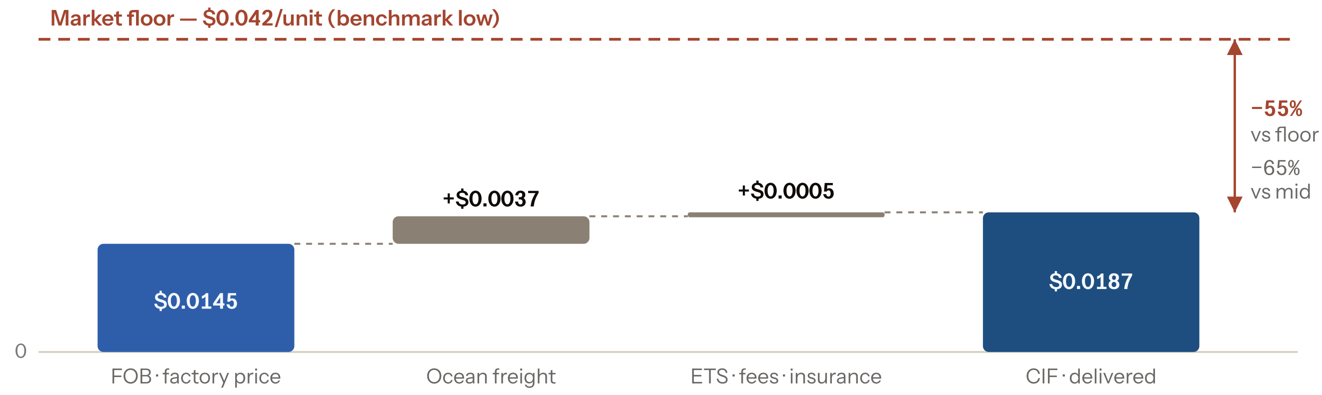
3 ML STANDARD · CIF ROTTERDAM · PER UNIT · JULY 2026

Supplier	FOB	+ ship · ETS · ins	CIF · full 40HQ	CIF · trial (LCL)
Kangyou	$0.0145	+$0.0042	**$0.0187**	$0.0197
Yesomed	$0.022	+$0.0042	$0.0262	$0.0273
Qiaosend	$0.0225	+$0.0042	$0.0267	$0.0289

FOB: verified in writing · valid 30 days from issue. **Freight layer:** $4,873/40HQ + EU ETS $168 + insurance 0.3% at July 20, 2026 — repriced at booking. Trial (LCL) is higher per unit — small shipments pay more per CBM.

Delivered cost builds to $0.0187 — the market floor sits 2.2× higher

3ml standard syringe, Kangyou, USD per unit, CIF Rotterdam · July 20, 2026



One waterfall per presented supplier in client editions. Benchmark floor: July 2026 EU market range, low end.

TWO PRICES, TWO CLOCKS

FOB — the factory's price. Verified in writing with each supplier. Valid 30 days from this report's date; it moves in weeks and is renegotiated with the factory. The sourcing decision anchors here — it is what was verified, and what you hold a supplier to.

CIF — the delivered price. FOB plus ocean freight, EU ETS, insurance — and any duties or trade measures. Freight reprices daily, surcharges quarterly, tariffs with policy. The CIF figures in this report are computed at July 20, 2026 rates; your forwarder re-quotes at booking.

Compare factories on FOB. Budget delivery on the day you book.

What the numbers say

Kangyou is the primary recommendation for standard disposables: lowest FOB, MDR to 2030. Yesomed is the only presented option for safety and auto-disable (WHO PQS) lines. Qiaosend covers needles, backup supply, and low-MOQ entry. The three are not interchangeable — they cover different parts of a supply chain.

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 the July 2026 EU market benchmark (tender corridors and import pricing). New spend uses verified factory-direct pricing from the three presented suppliers. A client edition rebases every row to the buyer's actual SKU mix and current buying prices — the client's own numbers are the base, not the benchmark.

CURRENT ANNUAL SPEND	NEW ANNUAL SPEND
$114K – $173K	$53,000
Estimated · July 2026 market benchmark	*Verified · cost-optimized allocation*

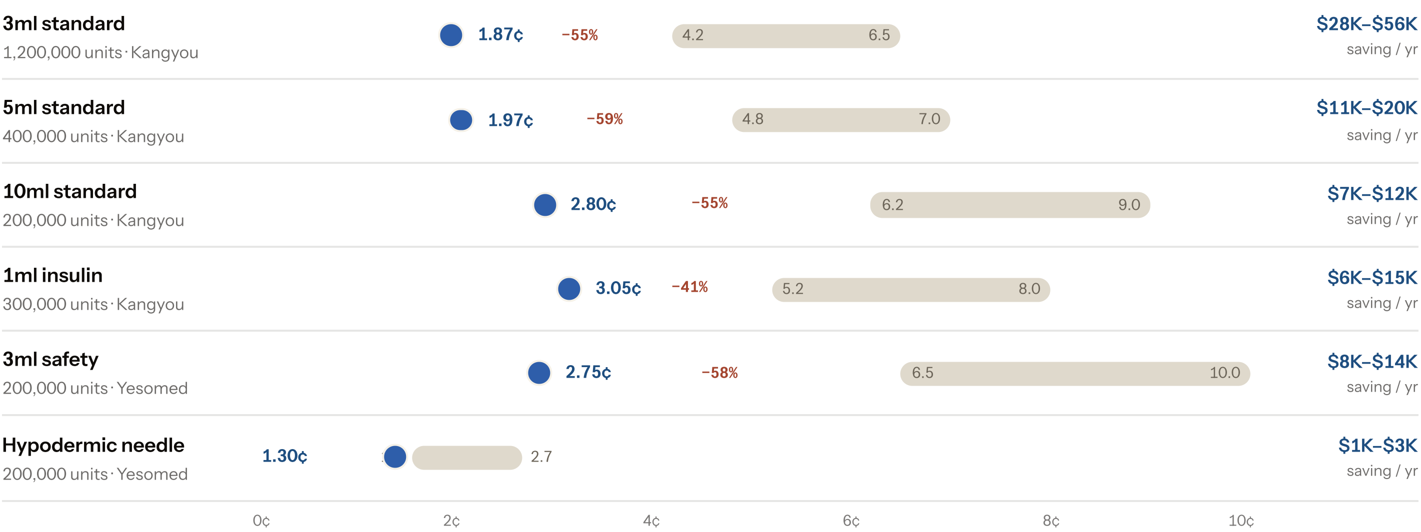
SAVED ANNUALLY

$61,000 – $120,000

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

Verified prices land 41–59% under the market band

Market benchmark range vs verified factory-direct landed cost · US cents per unit · July 2026



Band: July 2026 EU market benchmark. Dot: verified landed cost, CIF Rotterdam, Jul 20, 2026.

BREAKDOWN BY SKU CATEGORY

SKU CATEGORY	VOLUME	MARKET RANGE	RECOMMENDED	Y1 SAVINGS
3ml standard syringe	1,200,000	$0.042 – $0.065	Kangyou · $0.0187	$28K – $56K
5ml standard syringe	400,000	$0.048 – $0.070	Kangyou · $0.0197	$11K – $20K
10ml standard syringe	200,000	$0.062 – $0.090	Kangyou · $0.0280	$7K – $12K
1ml insulin syringe	300,000	$0.052 – $0.080	Kangyou · $0.0305	$6K – $15K

Safety syringe 3ml	200,000	$0.065 – $0.100	Yesomed · $0.0275	**$8K – $14K**
Standard hypodermic needle	200,000	$0.016 – $0.027	Yesomed · $0.0130	**$1K – $3K**

Market benchmark, July 2026, USD: EU commodity-syringe tender corridor $0.054–$0.16/unit with a realized $0.087 award; safety-engineered corridor $0.22–$0.65 (hospital-facing ceilings; distributor buy-side sits below). Savings are gross of switching costs and working capital, rounded to the nearest $1,000; rows sum to the headline. Allocation strategy follows.

Allocation Strategy

Two ways to deploy these findings.

Two ways to allocate 2.5M units across the three presented suppliers. Each optimises for a different priority.

STRATEGY A

Cost-optimized

SKU-by-SKU matching to lowest-cost qualified supplier. Maximum landed-cost savings.

Kangyou · 84% | Yesomed · 16%

ALLOCATION

Standard disposables + insulin · **Kangyou**
Safety syringes + needles · **Yesomed**
Backup / needle alternative · **Qiaosend**

ESTIMATED ANNUAL

~$53,000

$61K – $120K saved vs market benchmark

TRADE-OFFS

Three supplier relationships · separate QA processes and EUAR coordination per origin · best per-unit pricing on every SKU

STRATEGY B

Operationally-simple

Concentrated primary supplier with one backup. A cost premium of ~$12K/yr buys operational simplicity and supply priority.

Yesomed · 70% | Kangyou · 30%

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

~$65,000

$49K – $108K saved vs market benchmark

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

WHICH STRATEGY FITS

Strategy A suits buyers with procurement infrastructure to run three 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.

SUPPLIER 01 OF 03

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.

INSULIN SYRINGES

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

Standard disposable and insulin pricing for all three factories sits side-by-side in the matrix on page 07. Supplier pages carry only factory-specific lines and terms.

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 of the three presented — CE MDR valid to March 2030, EUAR held by Shanghai International Holding Corp. GmbH. A complete EU compliance chain. Product range includes CE MDR-certified surgical staplers (anorectal, linear, tube, skin) alongside syringes, infusion sets, and blood transfusion sets.

THE ECONOMIC CASE

Lowest FOB pricing for standard disposable syringes in this evaluation — $0.0145/unit on 3ml FOB Shanghai. At full 40HQ volume, landed cost to Rotterdam is $0.0187/unit. For a distributor whose primary requirement is standard disposables for EU hospital procurement, this is the primary recommendation. Pricing at MOQ stage is fixed. Volume terms — price adjustment, priority allocation, extended payment — open with a documented commitment of 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 03

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.

Standard disposable lines for all three factories are compared in the matrix on page 07; this page covers the specialty lines only Yesomed manufactures. 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 (300390) since 2014, which acquired Wuxi Yushou in 2015. The parent's capital structure and filings are public. Initial contact requires persistence. Once established, documentation, samples, and responses arrive without delay.

CERTIFICATION DEPTH

Yesomed's regulatory clearances span the most markets of the three presented. FDA clearance K053519 has been current since 2006. WHO PQS E008 covers auto-disable syringes only — it does not extend to needles or standard disposables. It is the only supplier in this evaluation holding WHO PQS alongside CE MDR and ISO 13485 — the combination EU safety-syringe supply requires.

WHERE TO USE THEM

Safety syringes — AD, RUP, and safety clip — are this factory's core capability: annual safety-syringe capacity of 500 million units, 24 domestic patents on the line. 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 first call. Volume terms open with a documented commitment — not at MOQ inquiry stage.

SALES CONTACT
PROVIDED UPON ENGAGEMENT
FOB PORT — SHANGHAI

SUPPLIER 03 OF 03

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 — LOWEST PRICING IN THIS EVALUATION

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

Standard-line pricing for all three factories: matrix, page 07. This page lists the needle lines Qiaosend leads on.

ASSESSMENT

Qiaosend is an export-only Sino-US joint venture; domestic China sales sit with the parent Qiaopai entity. CE MDR valid to July 2029, EUAR with MedNet EC-REP GmbH. Standard syringe pricing runs above Kangyou for comparable SKUs; needle pricing is the lowest in this evaluation. Position for this profile: needle supplier, backup line for syringes, and low-MOQ entry at 100,000 units.

SALES CONTACT — MERLIN

PROVIDED UPON ENGAGEMENT

FOB PORT — QINGDAO

Evaluated · Not Recommended

~~Zhejiang INI Medical~~

Zhejiang INI Medical Technology Co., Ltd. · Wenzhou, Zhejiang

FOB Ningbo / Shanghai · inimd.com

REMOVED AT PRESENTATION STAGE — MDR TRANSITION UNRESOLVED

01

MDR STATUS

MDD expired November 2025 — full MDR certificate pending

MDR application approved May 2024; the certificate has not yet issued. Under EU 2023/607 transitional provisions a legacy MDD certificate backed by a timely MDR application is generally deemed valid to 2027–2028, subject to conditions — but deemed-valid status is conditional, and NL/BE hospital tenders increasingly require an issued MDR certificate.

02

WHY PRICE DOES NOT OVERRIDE

A pending certificate is a supply risk, not a discount opportunity

Second-lowest standard-syringe FOB of the six evaluated ($0.0165 on 3ml) and the lowest MOQ (100,000 units). Neither offsets certification uncertainty for a hospital-channel profile under current EU MDR enforcement.

MOQ	FOB PORT	CERTIFICATIONS HELD
100,000 units	Ningbo / Shanghai	ISO 13485 (TUV Rheinland) · MDR pending
FACILITY 26,000m² · 400+ employees		

CONDITIONS FOR RECONSIDERATION

If the full MDR certificate issues, INI re-enters evaluation: its pricing and MOQ would place it as a secondary supplier for standard disposables and a primary source for specialty needle categories. Hielux monitors the certificate status and notifies the client on issuance.

Evaluated · Not Recommended

~~Guangdong Haiou~~

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

FOB Shantou · haiou.net.cn

DID NOT MEET PROFILE CRITERIA

01

MOQ MISMATCH

500,000 unit minimum — 2.5× above profile requirement

A first-order cash commitment out of proportion to this profile's volumes and risk tolerance.

02

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.

03

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 holds FDA, WHO PQS, CE, and ISO 13485. If direct engagement is established, samples are evaluated, and order volume justifies 500,000 units, Haiou becomes viable — particularly for safety syringe lines, where its 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 · 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.
02	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.
03	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.
04	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.

ADVISORY	EMAIL	SINGAPORE
Hielux Advisory	advisory@hieluxmt.com	+65 3 1255276

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 (July 2026). Certifications remain subject to renewal, suspension, or scope change after that date; Hielux re-verifies on renewal. FOB quotes are verified in writing and valid 30 days from issue. Freight, EU ETS, and duty components reprice continuously — daily for freight; CIF figures are calculated at July 20, 2026 and final delivered cost is set at booking. 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. Client reports are prepared for the named client only and are not for redistribution or resale; this sample is published by Hielux Advisory for evaluation, and the client profile shown is representative. Hielux Advisory holds no financial interest in any manufacturer featured in this report.

Prepared and signed by the Principal Consultant, Hielux Advisory — the trading name of Hielux Pte. Ltd. (UEN 202549390E), Singapore.