

Medical Equipment & PPE Sourcing Guide

Re&Source HUB — Hong Kong

Certified. Traceable. Compliant. Medical sourcing managed with precision at every step.

"When products protect workers or support patients, there is no room for error. Certification, traceability, compliance, and consistency are essential."

Who This Guide Is For

This guide is for healthcare operators, distributors, importers, NGOs, and procurement teams sourcing medical devices, personal protective equipment, and healthcare consumables from manufacturers in China and Asia. It covers the specific compliance, certification, and quality management requirements that distinguish medical and PPE sourcing from general product procurement.

Re&Source HUB works with buyers sourcing for regulated markets including the United States, European Union, United Kingdom, Australia, and the Middle East.

Why Medical & PPE Sourcing Requires Specialist Handling

Medical and PPE procurement carries a higher accountability threshold than standard consumer goods. Certification lapses, undisclosed supply chain changes, and inadequate traceability are not merely commercial risks — they carry regulatory, legal, and reputational consequences. Independent oversight throughout the supply chain is not optional; it is the responsible standard of care.

Re&Source HUB acts exclusively as the buyer's representative. The team conducts independent factory verification, maintains documentation throughout the production and export process, and provides the traceability records buyers need to demonstrate compliance to their own customers, regulators, and auditors.

What Re&Source HUB Covers for Medical & PPE

Service Area	What We Do
Certified Supplier Identification	Identify FDA-registered, CE-certified, and ISO 13485-compliant facilities matched to your product category
Factory Audit & Due Diligence	On-site factory audits covering manufacturing standards, QMS, and traceability protocols
Regulatory Mapping	Advise on applicable certifications and compliance requirements for the destination market

Service Area	What We Do
Price Negotiation	Negotiate pricing transparently, including certification fees, testing costs, and logistics
Technical Documentation	Manage tech pack submission, labelling requirements, and regulatory declarations
Third-Party Testing Coordination	Submit samples to accredited laboratories and share test reports with clients
Production Monitoring	Inspect batch consistency, quality management protocols, and traceability records during production
Pre-Shipment Inspection	AQL inspection of product quality, labelling accuracy, and documentation before release
Export Documentation	Certificate of conformity, test reports, customs declarations, and temperature-sensitive handling
Traceability Records	Batch and lot records retained and available on request post-delivery

Product Categories We Source

- **Personal Protective Equipment (PPE):** Face masks (surgical, N95/KN95, FFP2/FFP3), nitrile and latex gloves, protective gowns, face shields, safety goggles
- **Medical Devices (Class I & II):** Diagnostic equipment, monitoring devices, wound care products, mobility aids
- **Hospital & Clinic Consumables:** Syringes, IV sets, specimen containers, disposable instruments
- **Infection Control:** Hand sanitiser, surface disinfectants, sterilisation products
- **Rehabilitation & Mobility:** Wheelchairs, walking aids, orthotic supports
- **Dental Supplies:** Disposable dental products, instruments, and protective equipment

Certifications & Standards

Certification	Market	Applies To
FDA 510(k) / Registration	USA	Medical devices, Class II
CE Marking (MDR 2017/745)	European Union	Medical devices
UKCA	United Kingdom	Medical devices post-Brexit
ISO 13485	Global	Quality management for medical device manufacturers
EN 149	EU	FFP2/FFP3 filtering face masks
NIOSH N95	USA	N95 respirators
ASTM F2100	USA	Surgical masks
EN 455	EU	Medical gloves
EN 374	EU	Chemical protective gloves
TGA	Australia	Therapeutic goods

All certification requirements should be declared at the brief stage. Re&Source HUB verifies the current validity of certifications — not merely their existence — before recommending a supplier.

The Medical & PPE Sourcing Process — Step by Step

Step 1 — Requirement Specification & Compliance Brief

Define product requirements, target certifications, regulatory destination market, intended end-use, and volume needs. The team maps exactly what is required before any supplier is approached.

Step 2 — Supplier Identification & Regulatory Verification

Suitable manufacturers are identified from a network of FDA-registered and CE-certified facilities. Current certification status and compliance documentation are verified before any engagement.

Step 3 — Factory Audit & Due Diligence

For new suppliers or higher-risk product categories, on-site factory audits cover manufacturing standards, quality management systems, and traceability protocols. Audit reports are made available to clients.

Step 4 — Price Negotiation & Quotation

Pricing is negotiated with approved factories and presented transparently — unit price, certification fees, testing costs, and logistics included. No hidden charges.

Step 5 — Order Confirmation & Technical Documentation

All technical specifications, labelling requirements, regulatory declarations, and packaging standards are formally submitted. Export documentation requirements are established from the outset.

Step 6 — Pre-Production Sample & Compliance Testing

Samples are reviewed for conformity and submitted to accredited third-party testing laboratories where required. All test reports are shared with the client before bulk production is authorised.

Step 7 — Bulk Production & In-Process Monitoring

Production is monitored for compliance, quality management protocols, and batch consistency. Traceability documentation is maintained throughout.

Step 8 — Final Quality Inspection & Certification Check

Final AQL inspection verifies product quality, labelling accuracy, packaging integrity, and regulatory documentation. Certification validity is re-confirmed before goods are released for export.

Step 9 — Export, Compliance Documentation & Shipment

Full export documentation including certificate of conformity, test reports, and customs declarations is prepared. Temperature and handling requirements are confirmed for regulated products.

Step 10 — Post-Delivery Support & Traceability Records

Batch and traceability records are retained and available on request. Any compliance queries or product issues are managed directly with the factory on the client's behalf.

What to Include in Your Brief

- Product category and description
- Destination market and applicable regulatory framework
- Required certifications (FDA, CE, ISO, NIOSH, etc.)
- Intended end-use (clinical, occupational, consumer)
- Target quantity (initial order and projected annual volume)
- Target price (FOB or landed)
- Delivery timeline
- Any import broker or customs clearance requirements at destination

Typical Lead Times

Stage	Estimated Duration
Supplier identification & certification verification	1–2 weeks
Factory audit (if required)	1–2 weeks
Quotation and negotiation	1 week
Sample production and third-party testing	2–4 weeks
Bulk production	30–60 days
Pre-shipment inspection	1 week before shipment
Ocean freight	2–5 weeks depending on destination
Air freight	3–5 days

For urgent or pandemic-response procurement, expedited timelines can be structured. Communicate urgency at the outset.

A Note on Traceability

Every medical and PPE shipment managed by Re&Source HUB maintains a complete documentation trail: factory audit records, certification copies with validity dates, third-party test reports, pre-shipment inspection reports, and batch records. These records are retained by Re&Source HUB and made available to clients on request — providing the audit trail required by importers, healthcare operators, and regulators.

Key Terminology

Term	Meaning
CE Marking	Conformité Européenne — product meets EU health, safety, and environmental requirements
FDA Registration	United States Food and Drug Administration — registration required for medical devices
ISO 13485	International quality management standard specific to medical device manufacturers
AQL	Acceptable Quality Level — statistical sampling standard for pre-shipment inspection
QMS	Quality Management System — the documented system of procedures a manufacturer uses to ensure product quality
CoC	Certificate of Conformity — document from manufacturer or third party confirming product meets specified standards
EL	Electroluminescence testing — used for solar modules; not applicable here but included in the Solar guide

Starting Your Project

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Deal with one trusted partner instead of a hundred factories.