Refurbished Medical Equipment

A Practical Supplier Evaluation Checklist for Hospitals, Distributors, and Importers

Prepared for procurement teams, biomedical engineering departments, and distributors evaluating a refurbished medical equipment supplier — whether for a single purchase or an ongoing supply relationship.

Important note on scope and use: *This document is an original, independently written practical checklist reflecting generally accepted supplier-qualification and quality-assurance principles used in medical device procurement (informed by concepts in ISO 13485 supplier control and ISO 14971 risk management, summarized in the author's own words). It is a starting self-assessment tool, not a substitute for formal supplier audit, legal due diligence, or the destination country's regulatory requirements, which should be verified directly with the relevant authority or a qualified local regulatory consultant.*

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1. Why Supplier Evaluation Matters for Refurbished Equipment

Refurbished medical equipment can offer excellent value and extend access to care, but the safety and performance of the device depend heavily on the quality of the refurbishment process itself — not just the original manufacturer's design. Unlike buying new equipment directly from an OEM with a full factory warranty, a refurbished-equipment purchase is really a purchase of *two* things at once: the underlying device, and the supplier's quality process that returned it to service. A structured evaluation protects patient safety, budget, and long-term equipment reliability.

2. Company Credentials & Track Record

A. Company Credentials Checklist

Check Item	Result	Notes
■ Company is formally registered and licensed to operate in its home jurisdiction.	Y / N / Partial	
■ Company holds (or is actively pursuing) ISO 13485 certification for its quality management system.	Y / N / Partial	
■ Certificates (ISO 13485, ISO 9001, or others claimed) can be independently verified with the issuing certification body.	Y / N / Partial	
■ Years of operating history in medical equipment refurbishment/service specifically (not just general trading).	Y / N / Partial	
■ References available from other hospitals, distributors, or institutional buyers.	Y / N / Partial	
■ Company has documented export experience to your specific country/region.	Y / N / Partial	
■ Clear legal entity and contract terms — not an informal or unregistered intermediary.	Y / N / Partial	

3. Technical Process & Quality System

B. Refurbishment Process Checklist

Check Item	Result	Notes
■ Documented, standardized work instructions exist for refurbishment of the specific device category being purchased.	Y / N / Partial	
■ Refurbishment includes electrical safety testing aligned with IEC 60601-1 classification and IEC 62353 in-service test methods.	Y / N / Partial	
■ Functional/performance testing performed against the original manufacturer's specification, not just a basic power-on check.	Y / N / Partial	
■ Traceability maintained from donor unit through refurbishment steps to final unit (serial number, technician, test records).	Y / N / Partial	
■ Risk assessment performed for any modification beyond the original manufacturer's specification (component substitution, software updates).	Y / N / Partial	
■ Spare parts sourced from qualified suppliers, with used/reclaimed parts risk-assessed before reuse.	Y / N / Partial	
■ Cleaning/decontamination process appropriate to the device type documented and followed.	Y / N / Partial	
■ Final acceptance test results available for the specific unit being purchased (not just a general process description).	Y / N / Partial	

4. Documentation You Should Receive

C. Purchase Documentation Checklist

Check Item	Result	Notes
■ Test/calibration report for the specific unit (not a generic template), with measured values.	Y / N / Partial	
■ Certificate of conformity / refurbishment completion for the unit.	Y / N / Partial	
■ Original manufacturer's user manual (or a legitimate reproduction/translation).	Y / N / Partial	
■ Bill of accessories included with the unit, matching what was ordered.	Y / N / Partial	
■ Warranty terms in writing: duration, coverage scope, and what voids the warranty.	Y / N / Partial	
■ Return/complaint-handling procedure explained in writing.	Y / N / Partial	
■ Export documentation appropriate to your import requirements (invoice, certificate of origin, packing list, and any device-specific regulatory documents your country requires).	Y / N / Partial	

5. Regulatory & Compliance Fit for Your Market

D. Regulatory Fit Checklist

Check Item	Result	Notes
■ Supplier can confirm whether the specific device model is registered/recognized in your country, or can support you through that process.	Y / N / Partial	
■ Supplier can provide documentation needed for your country's import licensing process (see the companion regional regulatory orientation guide for examples).	Y / N / Partial	
■ Original device carried valid CE marking, FDA clearance, or another recognized approval before refurbishment (ask for evidence).	Y / N / Partial	
■ Supplier discloses clearly if any modification could affect the device's original regulatory classification or intended use.	Y / N / Partial	
■ Supplier is transparent about any prior recalls, field safety notices, or known issues associated with the specific model.	Y / N / Partial	

6. Logistics, Training & After-Sales Support

E. After-Sales Support Checklist

Check Item	Result	Notes
■ Delivery timeline and shipping/insurance terms clearly defined.	Y / N / Partial	
■ Installation support offered or clearly excluded (know which before you buy).	Y / N / Partial	
■ User training available for clinical staff, in an appropriate language.	Y / N / Partial	
■ Spare-parts availability and expected lead time disclosed for the device's expected service life.	Y / N / Partial	
■ Remote or on-site technical support options and response-time commitments defined.	Y / N / Partial	
■ Clear escalation path and contact person for post-sale technical issues.	Y / N / Partial	

7. Warning Signs (Red Flags)

The following patterns should prompt extra caution or a second opinion before proceeding with a purchase:

- Refusal or inability to provide unit-specific test results — only generic marketing claims.
- No documented refurbishment process, or a process that consists only of visual cleaning and repackaging.
- Reluctance to disclose the donor equipment's origin, age, or prior usage history.
- Pressure to close the deal quickly without time for independent verification of certificates or references.
- No clear warranty terms, or a warranty that is verbal only and not in the written contract.
- Inconsistent or evasive answers about the company's registration, certification, or export history.
- Prices dramatically below market average with no clear explanation (may indicate corners cut in testing or parts quality).

8. Simple Weighted Scoring Template

For comparing multiple suppliers objectively, score each category from 0 (not met) to 5 (fully met), multiply by the suggested weight, and sum for a comparable total. Adjust weights to reflect your own institution's priorities.

Category	Suggested weight
Company credentials & track record	20%
Technical process & quality system	30%
Documentation completeness	20%
Regulatory fit for your market	20%
After-sales support	10%

Reminder: *this checklist is a practical starting template for internal use. For high-value or high-risk equipment categories (e.g. imaging, life-support, surgical), consider a formal on-site or documented remote audit of the supplier's facility in addition to this checklist.*