Radiology Oncology Systems

RELIABILITY REFINED™

IMPORT/EXPORT REQUIREMENTS FOR USED MEDICAL EQUIPMENT ACROSS THE GLOBE

The global trade of used medical equipment is a complex and highly regulated process, shaped by varying national laws, customs procedures, and import/export tariffs. As healthcare systems around the world evolve, the need for affordable medical equipment has led to an increase in the international movement of pre-owned devices. However, each country has its own set of rules and regulations governing the import and export of these items, driven by concerns over safety, quality control, environmental impact, and public health.

Note:

The import and export regulations and licensing requirements outlined in this document are subject to change and may vary by jurisdiction, equipment type, and specific circumstances. While we strive to keep this information current, we strongly recommend consulting the appropriate governmental authorities or official trade resources, such as each country's Ministry of Health, Customs Authority, or Trade Ministry, for the most up-to-date and accurate information.

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NOTE: THIS INFORMATION IS SUBJECT TO CHANGE. PLEASE CONSULT OFFICIAL SOURCES FOR THE MOST CURRENT IMPORT/EXPORT REGULATIONS.

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NORTH AMERICA				
Antigua and Barbuda	Ministry of Health approval required for used medical equipment.	Used medical equipment must meet health and safety standards.	• Invoice, Bill of Lading, and health certification • CE Mark certification • Equipment may require inspection upon arrival by health authorities	
The Bahamas	Import permits are required from the Ministry of Health.	Used medical equipment must comply with local health and safety standards.	Commercial invoice, Certificate of Origin, Bill of Lading and technical documentation.	The Ministry of Health does not generally purchase used medical equipment.
Barbados	• Import license may be required for used medical equipment • Approval from the Barbados National Standards Institution (BNSI) may be necessary	Equipment must comply with health and safety standards.	Certificate of Origin, Bill of Lading, technical documentation.	
Belize	Import license required.	• Used medical equipment must be registered with the Ministry of Health • The equipment must meet local health and safety standards • Labeling and packaging must comply with Belize Bureau of Standards (BBS) regulations • Equipment may be subject to inspection for compliance with national health regulations	• Commercial invoice, Certificate of Origin, Bill of Lading and technical documentation • Possibly sanitary or phyto sanitary certificates	
Canada	• Medical Device Establishment License (MDEL) is required for importers of used medical equipment • Importers must ensure that foreign distributors or manufacturers have an MDEL	• Used medical equipment must comply with Health Canada's Medical Device Regulations (MDR) and Food and Drugs Act (FDA) • Devices must be safe, effective, and meet quality standards • All used devices must be free from contamination and have valid certifications	• Commercial invoice, Bill of Lading, Certificate of Origin, and technical documentation • Canada Border Services Agency (CBSA) enforces compliance with Health Canada regulations • Form B3 (Customs Coding Form) required for clearance	• Importation of used medical devices may be subject to stricter compliance checks • Bilingual labeling (English and French) may be required for packaging. • Specific language requirements for labeling may apply
Costa Rica	• Import permits required from the Ministry of Health • Certificates must include quantitative and qualitative analysis, good manufacturing practices, and free sale certificates • (U.S.- Only) U.S. FDA authorizations for medical devices are recognized without additional evaluation by the Ministry of Health	• Sanitary regulations require equipment to comply with local health and safety standards • Refurbished medical equipment must be registered with the Ministry of Health • (U.S.- Only) Costa Rican government accepts U.S. commercial and product standards • Certification to ISO standards is voluntary but can be beneficial • For imports from CAFTA countries, certification of the origin of goods must be presented, but no specific format is required	• Commercial invoices, Bills of Lading, and Airway bills are required • Additional documentation such as import permits and certifications • For electronic systems, utilize the TICA system must be used for tracking and Single Windows for streamlined processing • All import processing should be handled by a certified customs broker • Violations of documentation laws can result in heavy fines	

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NORTH AMERICA				
Cuba	• (U.S.- Only) Individual validated licenses from the Bureau of Industry and Security (BIS) are required for the export and reexport of medical devices to Cuba • (U.S.- Only) Medical devices are not eligible for License Exception Support for the Cuban People (SCP) • A sanitary registration or import license issued by the Ministry of Public Health is required	• Medical devices must meet Cuban technical, safety and sanitary standards. These standards typically require proof of quality (e.g. CE marking). Used or refurbished equipment will be subject to stricter scrutiny to ensure safety and suitability for healthcare use • (U.S.- Only) There is a general policy of denial for items subject to the EAR, but medicines and medical devices are typically approved for export to Cuba.	• (U.S.- Only) SNAP R online portal is used to submit export license applications to the BIS • D'VIAJEROS form Commercial invoice, Bill of Lading, Certificate of Origin, and technical documentation • Used medical equipment imports might be subject to customs inspections for verification of their purpose	
Dominican Republic (DR)	Import licenses are generally not required for used medical equipment.	• Public hospitals are not allowed to purchase used medical equipment but can accept it as a donation • Smaller clinics may import preowned equipment, typically requiring sanitary registration to ensure compliance • Medical equipment, including used devices, must comply with sanitary and quality standards enforced by the General Directorate of Medicines, Food, and Health Products (DIGEMAPS) • Ensure compliance with NORDOM 53 and NORDOM 407 standards for labeling • Labels must be in Spanish and include specific product details	• Customs Declaration Form • Commercial of Origin, Bill of Lading, and any documentation required by DIGEMAPS for sanitary compliance • Certification for CAFTA-DR preferential tariff treatment should include tariff classification, origin information, and certification date	
El Salvador	• Import licenses required • Ionizing radiation devices require a permit from the Radiation Protection Directorate at the Ministry of Health	Used or refurbished medical equipment cannot be older than 10 years.	• Commercial invoice, Bill of Lading, and other required documents • Customs requires specific documentation for CAFTA-DR preference and can request additional documents for trans-shipment	• Public institutions usually buy new equipment; private hospitals occasionally buy refurbished equipment. • Sale service and technical support are crucial; companies are encouraged to partner with local distributors
Grenada	Import license required.	No person may import medical products without a valid license.	• Applications for import licenses must be submitted via the ASYCUDA World System using Direct Trader Input (DTI) • Used medical equipment may undergo a physical inspection to ensure that it matches the information provided in the import declaration	False declarations can result in prosecution.

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NORTH AMERICA				
Guatemala	• Import permit required • Medical device must be registered with the Health Council	• Compliance with RTCA regulations for product standards and technical criteria is required, including packaging, labeling, and potentially safety standards • As part of the CAFTA-DR agreement, these regulations are harmonized across Central America, but local interpretation and enforcement may vary • Equipment must meet Ministry of Health standards	• Refurbished equipment must meet all local standards • Commercial invoice, Bill of Lading, Certificate of Origin, and technical documentation	
Haiti	Importers must obtain an import permit from the Ministry of Commerce.	No specific exemptions for used medical equipment.	• Importers must submit a digitized import notice form • Commercial invoice, Bill of Lading, Certificate of Origin, and technical documentation	
Honduras	• Registration through ARSA • Import permit and sanitary certificate from the General Directorate for Sanitary Regulation (DGRS) required • Veterinary medicines require a permit from SENASA	• Compliance with ARSA and DGRS regulations is mandatory for medical devices • ARSA issues sanitary registration numbers (SRN) for products • The SRN is valid for five years	• Complete customs forms and medical clearance forms at least three business days prior to importation • A Certificate of Origin must be presented to claim duty-free status under CAFTA-DR • Attention must be paid to documentation requirements due to ongoing restructuring of customs procedures	• Honduran customs are strict with the evaluation of certificates of origin, and errors can result in fines and non-CAFTA import duties
Jamaica	Import permit required for used medical equipment, reviewed by Pharmaceutical and Regulatory Affairs (PRA).	• Equipment must meet PRA's health and safety standards • Must be registered and approved before importation	• Importers must submit product info to PRA which evaluates and advises on requirements • Commercial invoice, Bill of Lading, Certificate of Origin, and technical documentation	
Mexico	• Importers must be registered in the Official Register of Importers (Padrón de Importadores) maintained by the SHCP • For used medical devices, an import permit must be requested from COFEPRIS • The import permit requires an invoice proving the equipment is not new and a document stating the device is functioning properly • Import permits are required for a small number of devices and these cannot be sold to a third party	• Compliance with Mexican product safety and performance regulations is required • Medical devices must have sanitary authorization from COFEPRIS • Starting August 1, 2023, compliance with the Complemento Carta Porte (Bill of Lading) Complement is required • USMCA rules for origin certification may apply	• Customs Declaration Form (Pedimento de Importación) • Commercial invoice (in Spanish), Bill of Lading, and documentation proving compliance with Mexican safety and performance regulations • Use of an authorized customs broker is required • Customs clearance can be time consuming	Import permits are mandatory for used medical devices; declaring them as spare parts or accessories is considered a bad practice and is not compliant with regulations.

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NORTH AMERICA				
Nicaragua	Importers must obtain sanitary registration from the Ministry of Health's Pharmaceutical office and pay relevant fees.	• Compliance with Nicaraguan health and safety standards is required • The Ministry of Health's Pharmaceutical Office requires documentation demonstrating the safety and effectiveness of used medical equipment • Ensure that all imported medical equipment complies with Nicaraguan technical and sanitary regulations	• Bill of Lading Packing List • Original invoice Declaration of invoice authenticity • Permits (if required) • Certificate of Origin (to determine applicability of CAFTA-DR and other trade agreements) • Registration as a taxpayer with DGI and provide proof of fiscal solvency	
Panama	• No special import licenses are required for used medical equipment • Operation License is required for entities involved in manufacturing, packaging, import, export, distribution, marketing, or storage. This license is valid for three years	• Goods must comply with the Panamanian Harmonized System (HS) or Tariff Nomenclature • Products must comply with technical specifications set by the National Interinstitutional Technical Committee (CTNI) • A Technical Verification Certificate is required for public institutions, valid for five years	• Medical devices require marketing authorization for import, distribution and commercialization, valid for ten years • Commercial invoice, Bill of Lading Certificate of Origin, export certificate and Packing List	
Trinidad and Tobago	An import license may be required for certain used medical equipment.	Products must comply with TTS76 labeling standards, including product description, country of origin, and safety information.	A customs broker is required for imports; submit CARICOM area invoice, supplier's invoice, Bill of Lading, C75/C76 form, Certificate of Origin, and any relevant health/sanitary certificates to customs for clearance.	Medical equipment is subject to inspection and may require certification for safety and compliance.
U.S. Export Regulations	• Export Control Classification Number (ECCN) Classification Code • Regulation Number BIS (Bureau of Industry and Security, located in the US Department of commerce) issues the BIS • 748P Application Form and the permit	• Compliance with U.S. • Export Administration Regulations (EAR) and Office of Foreign Assets Control (OFAC) requirements	• BIS 748P form • Detailed specifications of the equipment are required	

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SOUTH AMERICA				
Argentina	• Medical devices must be registered with ANMAT before import. Registration is valid for 5 years (renewed within 30 business days before expiration) • Import license (TAD system) is required from ANMAT	• Used/refurbished medical equipment allowed only if the equipment has been refurbished by the original manufacturer or by an approved technical service, certified via a detailed refurbishment technical report with tests, standards and affirmation device meets original specs • Devices must meet Administración Nacional de Medicamentos, Alimentos y Tecnología Médica's (ANMAT) GMP or MDSAP/ISO 13485 standards as per Disposition 3266-2013	• Technical documentation: Annex IIIA/B/C depending on classification of the equipment, Certificate of Free Sale (CFS), local GMP compliance, Commercial invoice, Packing List, shipping documents and Registration Certificate	• Recent deregulation (Decree 273/2025) removes bureaucratic barriers for general used capital goods, but medical equipment remains under strict exception and documentation requirements • Labels and instructions must be in Spanish
Bolivia	• No special licensing required for used/ refurbished medical equipment • Medical equipment treated the same as new • Registration with AGEMED required • Importers are required to submit three physical samples of the device to INLASA for verification	Must follow government procurement regulations for public sector purchases.	• Sworn Declaration Form: Required by the National Customs Office if the product does not require inspection Cost is 1% of FOB (Free on Board) product value • Product Verification: If required by inspection companies, the cost is 1.75% of the FOB product value • Pre-shipment Inspection: Not required for most medical equipment. • Bolivian Customs will inspect the equipment upon arrival • Commercial invoice, Certificate of Origin and Bill of Lading	
Brazil	• Medical Product Import License and Operating Authorization (AFE) required • Importers and equipment registration with ANVISA (Agência Nacional de Vigilância Sanitária)	• Refurbished equipment is not banned but subject to strict regulation: it must meet safety, performance, and hygiene standards equivalent to new equipment • The refurbishment must be performed by the original manufacturer or authorized technical service provider and be accompanied by a certification of conformity • Reprocessed single-use devices are not allowed for import • Used equipment that is not refurbished or lacks traceability/certification is prohibited	• The following documents must be submitted via the SISCOMEX system: commercial invoice, Bill of Lading, ANVISA import license, and Certificate of Origin • Certificate of Free Sale (CFS) and detailed refurbishment report required for refurbished goods • Customs clearance can take 15-60 days depending on device	• Items must be labeled in Portuguese and meet Brazilian standards • Devices imported for donation or humanitarian use require additional authorization from ANVISA and the Ministry of Health

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SOUTH AMERICA				
Chile	• All medical equipment (including refurbished) must be registered with the Institute of Public Health (ISP) under the Ministry of Health • Importers must hold a valid Sanitary Registration and be authorized by ISP	• Must comply with Chilean health regulations, including safety and efficacy standards • The ISP oversees these regulations and may require additional certifications	• Commercial invoice, Certificate of Origin, Bill of Lading, ISP registration (if applicable) and sanitary registration • Technical report and certificate of refurbishment recommeded for used medicament. Clearance is done via the SICEX platform • Equipment may undergo additional inspections to ensure compliance with national standards	• Importing used medical equipment can be subject to specific restrictions if the equipment is considered obsolete or hazardous • Labels must be in Spanish • Regular updates to import regulations may occur, so staying informed through official channels is crucial
Colombia	Sanitary registration from the Colombian National Institute for Food and Drug Surveillance (INVIMA).	• Colombian regulations on health, safety, and efficacy • INVIMA regulates these standards and may require additional certifications, particularly for used or refurbished equipment • Specific technical and operational standards to ensure they are safe and functional • Used equipment must be 5 years old or younger (Decree 4725 of 2005)	• Commercial invoice, Certificate of Origin, Bill of Lading, and the relevant sanitary registration • May be subject to additional inspections and checks to ensure compliance with national standards • Customs valuation may also include an assessment of the equipment's residual life and functionality	
Ecuador	• Private hospitals and clinics require a permit to import used equipment • Must be registered with the Ministry of Industry and Productivity's Quality Department	• Equipment must be refurbished and come with a one-year warranty • Must comply with Ecuadorian standards and obtain INEN 1 certificate	• Present the INEN • 1 certificate at customs • Submit all required registration and technical documents • Conformity Assessment required (INEN 1)	Only private entities (hospitals, clinics) can import used medical equipment.
Paraguay	• Importers must obtain an import license from the Ministry of Health • Additional permits may be required from the National Directorate of Sanitary Surveillance (DINAVISA)	• Used medical equipment must be labeled with the country of origin • Expiration dates must be clearly stated where applicable • Compliance with local health and safety standards is required • Import operations for used medical equipment must be processed through authorized banks with notification to the Central Bank of Paraguay	• The CET must be paid to Paraguay's customs authorities • If used medical equipment is re-exported to another Mercosur country, the CET must be paid again upon importation into that country • Documentation must be certified, and a customs broker must be employed for processing • Commercial invoices, Certificates of Origin, and cargo manifests, which must be certified by the Paraguayan consulate or at the Ministry of Foreign Affairs in Paraguay	

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SOUTH AMERICA				
Peru	Sanitary registry: managed by the Dirección General de Medicamentos, Drogas e Insumos (DIGEMID) under the Ministry of Health (MINSA)	Used medical equipment is only permitted for purchase by individual physicians for personal use, not for institutional use	• Commercial invoices, Certificates of Origin, and cargo manifests • Documents must be certified by the Peruvian consulate or the Ministry of Foreign Affairs in Peru • Equipment is subject to customs inspection upon arrival	The Peruvian market prefers new equipment with strong post sales support
Uruguay	Sanitary registration managed by the Ministry of Public Health (MSP).	• Used medical equipment must meet health and safety standards set by the Ministry of Public Health (MSP) • Compliance with local regulations and international standards is required • Equipment must be inspected and approved before use in healthcare settings • Importers must appoint a local representative or distributor who will be responsible for regulatory compliance and registration	• Commercial invoices, Certificates of Origin, and cargo manifests • These must be certified by the Uruguayan consulate or the Ministry of Foreign Affairs • Equipment is subject to customs inspection upon arrival • Documentation and compliance with regulatory standards must be verified	All documents must be written in Spanish.
Venezuela	• Required approval from the Ministry of Health (MINSALUD) • Import permits required and are managed by various ministries depending on the equipment type	• Import of refurbished medical devices is only allowed in the private sector • Used equipment must have been registered when new, and MINSALUD does not accept registration requests for used equipment • The local importer or distributor must manage this process	Customs documents must be in Spanish, including the commercial invoice, Bill of Lading, packing list, Certificate of Origin and any required special certificates.	• Importers must ensure technical support and service availability. • Invoicing is illegal and may lead to fines or auctioning of goods

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ASIA				
Afghanistan	• Requires business and activity licenses • Application must be made to the General Directory of Pharmacy Affairs • Pro forma statement required	• Must comply with the National Licensed Drugs List • Special cases may require approval from the National Medicine and Food Board	• Present Import Permit to Customs • Customs notifies the General Directory of Pharmacy Affairs of arrival • Quarantine and testing of samples • If quality is confirmed, an import permit is issued • Non-compliance results in seizure and disposal of goods	• The process can take 3 to 15 days • No quotas apply for licenses • Utilization of permits incurs no penalty • Permits are non transferable
Armenia	• Import and sale of medical equipment are authorized without state registration • However, updates and harmonization of local legislation are planned due to EAEU accession • A Certificate of state registration from another EAEU member state is recognized	• Must comply with EAEU technical regulations • Registration of medical products and their safety, efficacy, and quality must be managed, even if state registration is not required for equipment	• Customs declaration required with supporting documents, including commercial invoices • Online declaration process (DTI) must be used to reduce personal contact with customs officials	• Compliance with labeling standards is essential • Armenia's legislation is evolving to align with EAEU requirements, impacting the future import of medical equipment
Azerbaijan	Licenses from the Ministry of Health required.	• Mandatory registration since July 19, 2024, by the Center for Analytical Expertise • Devices classified by risk level; Class I devices do not require registration • Importers need a legal entity registered in Azerbaijan, suitable storage, qualified personnel, and a quality management system	• Import of unregistered devices is prohibited • Required documents include invoices, Packing Lists, Certificates of Origin, and licenses	• Labels must be in Azerbaijani and include device name, manufacturer's information, intended use, warnings, and expiration date • English or Russian labels can also be included
Bahrain	Bahrain's National Health Regulatory Authority (NHRA) prohibits the importation of used or refurbished medical devices.			
Bangladesh	Importers of used medical equipment must obtain Import Registration Certificates (IRC) from DGDA.	• Used medical devices are regulated under the Bangladesh Drug and Cosmetics Act of 2023 • These devices must comply with safety and quality standards	Certificate of Free Sale (CFS), ISO 13485, and additional technical documentation depending on registration status.	

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ASIA				
Bhutan	• Importers must secure an Import License from the DRA • Used medical devices must have documentation from the exporting country	• Governed by the Medicines Act of the Kingdom of Bhutan • DRA evaluates the quality, safety, and efficacy of all medical devices before approval • Compliance with international standards (e.g., ISO, CE marking) is often required • Registration is mandatory for all medical devices prior to importation	• Submission of required documentation, including import licenses, certificates of free sale or equivalent registration certificates, and quality assurance certificates, is mandatory • Customs may perform inspections and assessments to verify compliance with health regulations • Clearance times can vary; planning ahead is advisable to avoid delays	• DRA is working to improve regulatory infrastructure, including laboratory capabilities • Challenges include human resource limitations and the need for more robust testing facilities • Importers are encouraged to partner with local experts to navigate the logistics of Bhutan's mountainous terrain effectively
Brunei Darussalam	Import permit required.	• Used medical equipment must comply with regulations under the Ministry of Health and possibly the Brunei Medical Board • Additional approvals may be needed if the equipment is considered critical for health services • Importers must register with the port of entry	• Importers must submit completed customs declaration forms via the Brunei Darussalam National Single Window, along with supporting documents (invoices, packing lists, etc.) • Certificates of Origin and analysis may also be required	• All imports must bear appropriate labelling and documentation • Importation of medical supplies must comply with halal standards, where applicable
Cambodia	Medical devices must be registered with the Department of Drug and Food (DDF) and must have a medical device registration license.	• Imported medical products must undergo registration for laboratory testing • The registration process can take three to six months, with certificates valid for three years • Companies must reapply six months before expiration • Registration ensures compliance with safety and quality standards • Unregistered imports can incur fines or bans • Only Cambodian companies can import medical devices and IVDs	• The import process is facilitated through the Cambodia National Single Window (CNSW) portal • Companies must also hold a Certificate of Corporate and Import-Pharmaceutical License from the Ministry of Health	• Temporary imports are allowed under specific conditions, and importers may need to pay a security deposit for duties • Fines for importing unregistered medical devices can reach up to KHR 10 million (approximately USD $2,500) and may include imprisonment or confiscation of devices
China	No importation of used and refurbished medical equipment is allowed except for demonstration, exhibition, or non-clinical training purposes and under special approval.			

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ASIA				
Georgia	No import license required.	• Governed by general health regulations, with limited specific regulations for used medical equipment • Compliance with safety and quality standards may be advised • No registration is required for most used medical equipment • Specific categories (like dental materials) may require registration	• Customs require shipping documentation that includes a thorough description of the equipment • The import process is generally straightforward with minimal inspections	• The healthcare market is largely driven by out-of-pocket payments, influencing demand for affordable equipment
India	No importation of used or refurbished medical equipment is allowed, except for limited use under Rule 91 of the MDR 2017, such as for demonstration, training, or research and development purposes.			
Indonesia	No importation of used and refurbished medical equipment is allowed, except for non-clinical demonstration or exhibition devices, which require special approval.			
Iran	• (U.S.-Only) A license from the Bureau of Industry U.S. and Security (BIS) is required for most items on the Commerce Control List (CCL) • (U.S.-Only) OFAC authorization is necessary for exports to Iran • General Trade License required	• The Iranian Food and Drug Administration (IFDA) oversees medical device imports • Registration involves appointing a local representative • The IMED system is used for registration • Devices are classified by risk • Compliance with technical standards • Documentation review for safety and performance	• Appoint a representative in Iran must be appointed to manage the import process • An electronic request through IMED must be submitted, with complete required documentation, and undergo compliance assessments must be completed	
Iraq	• Registration of the foreign supplier at the Ministry of Health (MOH) Registration Board • For each consignment to the private sector, documents must be presented before an import license is issued by the MO 510(k) Number • (U.S.-Only) 510(k) Number	• Medical equipment must adhere to Iraqi standards enforced by the Central Organization for Standards and Quality Control (COSQC) • Marking requirements include as country of origin and date of manufacture/expiration	• Local chamber of commerce stamp • State Secretary of State, Department of State authentication • Stamp from the Iraqi Commercial Attaché in Washington, D.C. • Bill of Lading	• KIMADIA, the government company responsible for public health sector imports, operates a tender procurement system • Understanding KIMADIA's processes and having a local representative can be advantageous • Corruption is a significant issue • (U.S.-Only) With 31 CFR Chapter five lifted and the institution of section 576, open exchange with Iraq has become legal

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ASIA				
Israel	License required.	• All medical devices must be registered with the Medical Device Division (AMAR) of the Ministry of Health • Approvals such as FDA's 510(k), CE Mark, or others from recognized countries are necessary for registration • Must be OEM-refurbished or certified by an authorized body and meet original safety specs	• Imports must go through MALAM customs system, with required paperwork: invoice, certificate of origin, AMAR registration, CFS and refurbishment documentation • Customs classification is key; consult a customs broker for assistance is recommended • Ruling classification requests can be made to Customs	Labeling must be in Hebrew and include warnings if applicable.
Japan	• Import permit is required after declaring the goods to the Director General of Customs	• Used medical equipment must comply with the Pharmaceuticals and Medical Devices Act (PMD Act) • Customs evaluates the product's suitability for import, ensuring it meets safety and compliance standards set by Japanese regulations • Certain used medical equipment may require additional regulatory approvals based on health regulations, specifically from the Ministry of Health, Labor, and Welfare (MHLW)	• Required documents include the Import Declaration Form, commercial invoice, and Packing List • The consumption tax of 10% (standard rate) or 8% (reduced rate) is calculated on the customs value plus any customs duty	
Jordan	No importation of used or refurbished medical equipment is allowed, except for training or demonstration devices under temporary import licenses for exhibition or educational purposes.			
Kazakhstan	Importers must obtain a license for medical equipment.	• Compliance with EAEU Technical Regulations is necessary for imported medical products • Certain items (e.g., hazardous materials) are prohibited	• Full customs declaration required within 30 days: brief declaration within 24 hours after the crossing of the border • Customs declaration must be filed by local entities only • ATA Carnets can be used for temporary duty free imports for exhibitions and trade fairs • A certificate of conformity may be required	• Import of used medical equipment is subject to additional scrutiny • A traceability system is in place for medical products; serialization required by 2023 • Importers may need to adhere to specific labeling guidelines for medical devices • All products must be labeled in Kazakh and Russian
Kuwait	• Import licenses are required from the Ministry of Commerce and Industry, valid for one year (renewable) • Registration with the Kuwait Chamber of Commerce and Industry (KCCI) is necessary • Local agents handle customs clearance	Compliance with international standard.	• Commercial invoice, Certificate of Origin, Packing List and Bill of Lading • Customs valuation follows the WTO Customs Valuation Agreement, primarily using transaction value	(U.S.-Only) U.S. companies should work with local partners to navigate registration and import processes effectively.

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ASIA				
Kyrgyzstan	• Importers must obtain state registration from the Ministry of Health • Registration involves submitting an application, dossier, samples, paying a fee, and passing safety and quality checks • The registration certificate is valid permanently; no renewal is needed • A foreign manufacturer needs an authorized representative in Kyrgyzstan	• Governed by the EAEU Customs Code (Articles 8, 89, 108) • Products must have labeling in Russian and/or Kyrgyz	• Standard customs, clearance and control procedures per EAEU Customs Code • Official translation of documents into Russian may be required	
Lao People's Democratic Republic	No importation of used or refurbished medical equipment is allowed, except for government-approved donations or imports for disaster relief.			
Lebanon	No importation of used and refurbished medical equipment is allowed.			
Malaysia	Specific permits and licenses are required for the importation of used medical equipment.	• Importation of used medical equipment is allowed; however, the public healthcare sector does not procure used equipment • Compliance with SIRIM QAS certification may be necessary	• Required documentation includes: invoice, Packing List, delivery letter, insurance certificate, Bill of Lading/Airway Bill, and Customs Form No. 1 • Duties and taxes must be paid in advance	• Demand for used medical equipment comes primarily from small healthcare practitioners • Malaysia follows the Harmonized Tariff System for classification
Mongolia	• An import license must be obtained to carry out the import of medical devices • Diagnostic medical devices are subject to additional registration requirements • The procedures for issuing licenses are governed by the Health Minister's Order No. A/407 (November 1, 2017) • Applicants must provide a range of documents, including agreements with suppliers and certification of compliance with international standards	• Diagnostic medical devices must be registered according to the Order of the Ministry of Health No. 13 (January 15, 2015) • The issuance of licenses is regulated under various laws, including the Law on Medicines and Medical Devices	• Dossier preparation for registration must adhere to national specific requirements • Applications for licenses must be submitted electronically, including detailed information on the imported products • The Center for Health Development monitors and reports on imports and exports quarterly • License applications are reviewed within five working days, and license holders are responsible for the accuracy of the submitted information	
Myanmar	• Register as a company authorized for international trade • Obtain Importer Registration Certificate (valid for up to five years; fee: MMK 200,000 + MMK 3,000 online) • Amendment of certificates: MMK 300 per entry • Extension of registration must be applied prior to expiry	• Medical device registration through Myanmar FDA is mandatory • Compliance with ISO 13485:2016 required • Registration is classified by risk (Class A to D) • FDA recommendation is needed for importing medical devices and cosmetics • Import restricted for certain goods without approval	• Required documents: Authorization letter, free sale certificate, manufacturing license, ISO certificate, etc • Registration with the Directorate of Trade is necessary for import business • Customs duty and commercial tax collected at the point of entry	

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ASIA				
Nepal	• No import license required for used medical equipment • Must show general export/import permits and taxpayer's certificate • If imported directly, provide corporate registration certificate and taxpayer's certificate for customs clearance	• Must comply with standards set by the Nepal Bureau of Standards and Metrology (NBSM) and the Department of Drug Administration • No special labeling required, but packaging must indicate country of origin	• Commercial Invoice, Customs Declaration Form (CDF) • Certificate of Origin Packing List • Airway Bill Authorization Letter (for exported items) • Copy of Export License (if applicable) • Foreign Exchange Declaration Form • Photocopy of Income Tax Registration Certificate • Letter of Credit or Advance Payment Statement	
Oman	• Registration of medical devices is not yet implemented; guidelines are still in draft form • Medical devices must be listed in the Medical Device Control Department databases	• Oman harmonizes standards with the GCC through the Gulf Standards Organization (GSO) • The Directorate General of Specifications and Metrology (DGSM) oversees standardization and conformity assessment	• The Bayan system facilitates efficient customs clearance • Required documents include commercial invoice, Bill of Lading/ Airway Bill, and relevant permits	
Pakistan	• Importers must obtain authorization from the Drug Regulatory Authority of Pakistan (DRAP) before importing medical devices • Radioactive equipment requires approval from the Pakistan Nuclear Regulatory Authority	Used medical equipment must comply with standards set by drap and the Pakistan Standards and Quality Control Authority (PSQCA).	• Bills of Lading invoices • Packing Lists Certificates of Origin • Letters of credit insurance certificates	
Qatar	Import licenses are required, issued only to Qatari nationals or Qatari partners, registered with the Ministry of Commerce and Industry.	• Used medical equipment must comply with Qatari • Equipment must meet safety and efficacy requirements as per the Ministry of Public Health • Health certificates may be required depending on the equipment type	• Submission of customs declaration • Bill of Lading, Certificate of Origin, Pro Forma invoice, and import license is necessary • Goods are subject to inspection at customs	The HS Code and country of origin must be clearly marked.
Saudi Arabia	• Import license required • For medical devices intended for demonstration or training purposes, specific documentation must be submitted, including a classification certificate and declaration of conformity	• Used medical equipment must conform to Saudi standards • Devices for demonstration/training purposes do not require Medical Device Marketing Authorization but must include labels indicating their intended use	• Importers must complete "FASAH" platform procedures by submitting necessary documents and a customs declaration at least 48 hours before arrival • Required documents include a commercial invoice, Bill of Lading, and Certificate of Origin • For demonstration devices, additional documents like an attestation and labeling must be provided	Only Saudi nationals may import goods for resale, however, foreign entities may trade their manufactured products.

NOTE: THIS INFORMATION IS SUBJECT TO CHANGE. PLEASE CONSULT OFFICIAL SOURCES FOR THE MOST CURRENT IMPORT/EXPORT REGULATIONS.

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
ASIA				
Singapore	• Special import licenses are required for medical devices • Compliance with specific regulations by the Health Sciences Authority (HSA) is mandatory	• Importation of used and refurbished medical equipment is permitted but must meet the regulatory requirements based on Global Harmonization Task Force (GHTF) recommendations • Recognized independent reference agencies include the USFDA, EU, Health Canada, TGA, and Japan's MHLW • Compliance with Singapore's Good Laboratory Practice (GLP) regulations may apply depending on the equipment type • Products may need to be tested and certified to ensure they meet local requirements	• Inward declaration is required for all imported refurbished medical equipment • Customs value is based on the CIF and transaction value	There is currently limited or no demand for used medical equipment in Singapore.
South Korea	Only licensed importers certified by the MFDS can import.	Used equipment requires 100% inspection at the importer's facility.	• Import declaration, invoice, Certificate of Origin • Safety, performance, intended use and MoA documents	• The market for used medical equipment is limited. • Registered devices can be imported for research, testing, or personal use under special conditions
Sri Lanka	• Must appoint a local authorized representative for registration and compliance • Import license application required after registration	• Medical devices must meet stringent standards for chemical, physical, and biological properties • Infection risk minimization and safety in construction and environment are mandatory • Compliance with measurement accuracy and radiation protection standards is essential • Energy source reliability must be ensured for devices with energy connections	• Submit certified shipping documents and customs declaration forms to the Sri Lanka Department of Customs • Original documents required within 30 days for clearance of goods shipped under DP/DA terms • For advanced payment (AP), submit proof of payment	
Syria	No importation of used or refurbished medical equipment is allowed.			
Tajikistan	• A permit is required from the State Health and Social Protection Service • Medical equipment must be registered with the state • Registration includes submitting an application, a registration file, and five sample copies • Certificate of conformity allows the use of a conformity mark	• Governed by the Law of the Republic of Tajikistan "On Medicines and Pharmaceutical Activities" and Decree No. 736 • Product labels must be in Tajik and Russian, including product names, manufacturer, country of origin, production date, expiration, storage, nutrition data, and usage instructions	• Importer's certificate of registration • Taxpayer identification number • Customs Cargo Declaration (in English) • Additional documents may include contracts, shipping documents, and various certificates depending on the product type	Import process can be complex; actual procedures may differ from published regulations.

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
ASIA				
Thailand	No importation of used and refurbished medical equipment is allowed, except for devices intended for temporary exhibitions or trade shows, non-clinical research or demonstration purposes, or humanitarian or disaster relief with prior approval.			
Turkmenistan	• A registration certificate from the State Registration Center for Medicinal Products of the Ministry of Health is required • A comprehensive registration dossier is required	• Registration dossiers must include detailed documents confirming legal status, production conditions, compliance with national and international standards, and safety/efficacy • The registration process includes submission, review, and issuance of a certificate valid for 5 years	• Contract registered at SCRME: Must specify goods, origin, currency, item price, and total price • Bill of Lading/ CMR: Required for transportation verification • Certificate of Origin and Quality: must be obtained from the Turkmenistan Chamber of Commerce and Turkmen Standards • Customs Declaration: Buyer usually responsible; service fee of 0.2% of contract price • Additional licenses may be needed based on product type (e.g., alcohol, electronics)	• Any changes to registered medical devices must be submitted within 30 days of approval; approval may take between 1 to 3 months • Registration must be initiated 3 months before expiration of the current certificate and typically takes 3 to 4 months
United Arab Emirates	No importation of used or refurbished medical equipment is allowed, except for training or demonstration equipment that can only be imported temporarily for non-clinical use with explicit MoHAP approval.			
Uzbekistan	Mandatory registration with the Ministry of Health.	• Registration overseen by the Ministry of Health • Devices classified into four categories (Class I, IIa, IIb, III) based on risk • Compliance with ISO 13485 standards is required	• Registration timeline is 6 to 12 months, with a five year validity • Pre-shipment inspections may be advisable to ease customs clearance	Customs clearances can be conducted at various locations upon request.
Vietnam	No importation of used or refurbished medical equipment is allowed, except for training or demonstration equipment that can only be imported temporarily for non-clinical use with explicit MoHAP approval.			
Yemen	• Importers must have valid licenses • Public health institutions equipment through a tendering system	• Equipment must not be more than 8 years old • Used equipment must be in good condition	• Goods must be cleared within 15 days from submission of the Single Administrative Document (SAD) • Goods left uncleared for 90 days may be auctioned • Additional documents may be required	

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COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Albania	• Import license required • Used medical equipment must be registered with the National Centre of Drugs and Medical Equipment before importation	• The import of used medical equipment is subject to sanitary and technical regulations set by the Albanian authorities, aligned with EU regulations • The importer is responsible for ensuring the quality and safety of the equipment, with the appropriate certificates of analysis and origin required for customs clearance	• A customs declaration must be filed with supporting documentation (e.g., invoices, certificates, etc.) • Customs authorities may conduct inspections to ensure compliance with import regulations and health standards • Required documents include: Certificate of Origin, Certificate of Quality, Certificate of Analysis, Invoice, and Transportation Documents (CMR, BL, AWB)	A description of the sanitary characteristics of the equipment is required to ensure safety compliance.
Austria	May need to be registered with the Austrian Medical Device Registry.	• Used and refurbished devices must meet the same safety, performance, and labeling standards as new devices • CE mark	• Commercial Invoices, Packing Lists, and Certificates of Conformity (CoC) • EORI number is required	
Belarus	• (U.S.-Only) License Exception MED allows the export, reexport • (U.S.-Only) Country transfer of EAR99 medical devices (low-tech medical products) to Russia, Belarus, and the occupied regions of Ukraine • All medical devices (new or used) must undergo state registration with the Belarus Ministry of Health prior to importation	• Military end users in Belarus are prohibited from receiving certain medical items • The Consolidated Screening List (CSL) should be consulted to verify that parties involved in the transaction are not subject to U.S. sanctions or license requirements • (U.S.-Only) Parts, components, accessories, and attachments must be exclusively used for EAR99 medical devices • Exporters must implement due diligence measures and maintain documentation for five years • Used equipment must be included in the State Register of Medical Devices in Belarus to be allowed for use • Used medical devices must undergo health and safety checks by the Ministry of Health or other regulatory bodies • Used equipment must be certified for safety and functionality before importation	• All used medical equipment must be declared to Belarusian Customs upon entry • The declaration should include the import license, invoice, packing list, and certificate of conformity. Pre • Pre-License Checks (PLC) or Post-Shipment Verifications (PSV) may be required for shipments to ensure that the items are used as stated in the license application • Exporters must provide detailed technical descriptions and end user information • Used medical devices may be subject to a physical inspection by customs officers to verify compliance with health and safety standards. conformity assessment • Conformity assessment • Certification of refurbishment might be required	• (U.S.-Only) U.S. sanctions on Belarus have tightened since the invasion of Ukraine, with restrictions on various goods, including medical equipment • (U.S.-Only) Exporters should be aware of the "red flags" or warning signs that may indicate potential violations of EAR • Used medical devices from the EU may require the CE marking to comply with EAEU standards • If from non EU countries, additional local certification may be necessary

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Belgium	• Refurbished devices must be authorized by the Federal Agency for Medicines and Health Products (FAMHP) before they can be used in Belgium • CE mark required for all devices (new and refurbished) • In some cases, depending on the nature of the equipment, a special import license or permit may be required from Belgian health authorities (e.g., Federal Agency for Medicines and Health Products, FAGG/AFMPS)	• Used and refurbished devices must meet the same safety, performance, and labeling standards as new devices • Must comply with EU Medical Device Regulation (MDR 2017/745) and in Vitro Diagnostic Medical Device Regulation (IVDR 2017/746) • If the used medical equipment is being imported from outside the EU, a Responsible Person (based in the EU) must be appointed	• Standard EU customs procedures apply for used medical equipment. The importer must submit a customs declaration to Belgian Customs (Federal Public Service Finances) • This declaration must include information on the equipment's HS code, value, and country of origin • Products must be classified according to the Combined Nomenclature (CN) for import into the EU	Liability concerns may make public health institutions cautious about purchasing used or refurbished devices.
Bosnia and Herzegovina	Must include a customs declaration in Bosnian, Serbian, or Croatian with relevant documents (e.g., invoice, shipping docs, quality control certificates).	Testing and certification required for used medical equipment.	• Bill of Lading, Insurance Certificate, etc. Conformity assessment • CE marking or equivalent	
Bulgaria	Bulgarian decree required.	CE mark must meet EU certification requirements and comply with Bulgarian Drug Agency standards.	• Invoice, Certificate of Origin, transport documents • Economic Operators Registration and Identification (EORI) number	Maintenance contracts must be secured for used medical equipment.
Croatia	Quality control certificates may be needed.	• CE mark must comply with EU CE certification requirements • Labels must be in Croatian and meet local product standards • Used medical equipment classified under the EU classification system	• Single Administrative Document (SAD) for customs clearance • Commercial Invoice, Packing List, and Certificates of Origin • Certificates of Conformity (CoC) • An EORI number is needed to import goods into the EU	Goods move freely among member states of EU.
Cyprus	Importers must notify the Cyprus Medical Devices Authority (CyMDA) about the used medical equipment being placed in the market.	• Must comply with EU medical device regulations, ensuring devices meet safety standards • Labeling must be in Greek for layperson use devices • English is accepted for professional use devices	• Commercial Invoice, Packing List, and Datasheets • Compliance with customs regulations is mandatory, including obtaining an EORI number if importing from a third country	
Czech Republic	No special import licenses for medical devices.	• CE mark • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	

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COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Denmark	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Economic Operator Registration and Identification (EORI) number is requiredCustoms IT systems and the Union Customs Code (UCC) are implemented with full transition by 2025 • Country of origin may need to be indicated	Labels must be in Danish or in a language with minimal spelling differences (Norwegian or Swedish).
Estonia	No special import licenses for medical devices.	• CE mark Safety and labeling standards must be met • Used medical equipment classified under the EU classification system. • Non-EU manufacturers must appoint an Authorized Representative within the EU	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity (CoC) • An EORI number is needed to import goods into the EU	• Labeling must be in Estonian • Used equipment, must be registered or notified for market access
Finland	No special import licenses for medical devices.	• Devices must be registered with Valvira (National Supervisory Authority for Welfare and Health) CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Non-EU manufacturers must appoint an Authorized Representative within the EU	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU • Valuation declaration for items exceeding EUR 5,045.64, must be provided	• All used medical equipment must have clear labeling in Finnish and Swedish, including product name, manufacturer, and contents • Serious incidents involving the device must be reported within 10 days
France	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	All labeling must be in French.

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Germany	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Must comply with RoHS and WEEE • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Greece	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Hungary	• No special import licenses for medical devices • License might be required by Hungarian Trade Licensing Office	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • ISO 13485 certification is required for QMS • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Non-EU manufacturers must appoint an Authorized Representative within the EU	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Iceland	No special import licenses for medical devices.	• CE mark Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration must be submitted within 3 months of arrival • Declaration of Conformity • An EORI number is needed to import goods into the EU	Relabeling may be required to meet Icelandic language requirements.

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Ireland (Republic of)	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must submit a Summary Declaration for used medical equipment • Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Italy	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	• Medical devices are subject to oversight by the Italian Ministry of Health (USMAF SASN) • Labeling must be in Italian
Latvia	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	Labeling must be in Latvian.
Liechtenstein	Notification required for first time import.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Used medical equipment that does not meet Swiss market requirements must be documented and registered with the Office of Public Health	• Goods enter Liechtenstein through Swiss border • Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	Labeling must be in German.

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Lithuania	All medical devices (including used) require registration with the competent authority.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration CIPL, Datasheets • Declaration of Conformity • An EORI number is needed to import goods into the EU	Labeling must be in Lithuanian.
Luxembourg	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system. Non EU manufacturers must appoint an Authorized Representative within the EU	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	Documentation must be submitted in Luxembourgish.
Malta	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system. Non EU manufacturers must appoint an Authorized Representative within the EU • UDI assigned, devices registered in EUDAMED	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	Labeling must be in Maltese/ English.
Moldova (Republic of)	Import permits may be required for medical equipment.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met	• Customs declaration must be submitted electronically • Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration	• Labels must be in Romanian with specific product details • Deferred payment for customs duties available from 2024

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Monaco	Import permit from the Ministry of Health may be required for some medical products.	• Customs clearance in Monaco is processed through French customs • CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Health department authorization if applicable	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Montenegro	Import permits may be needed, particularly for medical devices with health related risks.	• Customs duties are assessed based on the contract price • CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Netherlands	No special import licenses for medical devices.	• Customs duties are assessed based on the contract price • CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
North Macedonia (Republic of)	No special import licenses for medical devices.	• Customs duties are assessed based on the contract price • CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • The EC Conformity certificate is required and valid until its expiration	• Registration process for used medical devices takes about 90 days Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Norway	No special import licenses for medical devices.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Unique Device Identification (UDI) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Reprocessing of single-use devices is prohibited	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	All relevant documentation (conformity, safety notifications) must be in English or Norwegian.
Poland	No special import licenses for medical devices.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Devices must be registered with the Office for Registration of Medicinal Products if required	• Declaration to Customs using CN (Customs Nomenclature) classification • Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Portugal	No special import licenses for medical devices.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746); enforced by INFARMED in Portugal • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Romania	The importer may need to notify or register the device with ANMDMR (National Agency for Medicines and Medical Devices of Romania), especially if it is a refurbished or used item.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	
Russia (Russian Federation)	• (U.S.-Only) License Exception MED allows the export, reexport, and in Country transfer of EAR99 medical devices (low Tech medical products) to Russia, Belarus, and the occupied regions of Ukraine • All medical devices - whether new, used, or refurbished - must be registered with Roszdravnadzor, Russia's Federal Service for Surveillance in Healthcare, before importation • An import permit for registration purposes must be issued by Roszdravnadzor under Order No. 7n (2012)	• Items must be for civilian use; military or government use prohibited • Due diligence required to ensure the equipment is for civilian medical facilities providing direct patient care • Users (Russian and Belarusian Ministries of Defense) are restricted • Once registered via EAEU procedures, the device must bear the EAC mark and can be marketed freely across Russia and other EAEU nations	• (U.S.-Only) Applications evaluated by U.S. agencies to assess risk of diversion Requires End Use/User Statements Specific Harmonized System (HS) Codes and item descriptions required for efficient review. • Registration certificate; Technical dossier (including test reports, IFU, QMS); Invoice, Packing List, Certificate of Orgin; Test and Safety Certification evidence	
Serbia	• Import licenses required for non-registered medical devices	• CE mark • Must meet Serbian safety and technical regulations, including Serbian conformity mark for non EU good Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Goods must be declared via the Unique Customs Document; use of NCTS for EU based imports • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Slovak Republic	Required certification from the Slovak Institute for Drug Control (SUKL) for used medical equipment, based on European certification.	• CE mark • Compliance with the Union Customs Code (UCC) • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • -Declaration of Conformity • An EORI number is needed to import goods into the EU	
Slovenia	No special import licenses for medical devices.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU.	Local Slovene language required for equipment details.
Spain	No special import licenses for medical devices.	• CE mark • Registration in the EUDAMED system is necessary • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system. Non-EU manufacturers must appoint an Authorized Representative within the EU • No local testing required	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
Sweden	No special import licenses for medical devices.	• CE mark • Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • Equipment must meet Swedish Medical Products Agency (Läkemedelsverket) standards for medical devices	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	CE marked devices can be placed on the market without additional local permits, but they must be registered in the EU's EUDAMED database.
Switzerland	No special import licenses for medical devices.	• CE mark • Compliance with Swiss MedDO (for medical devices) and IvDO (for in Vitro diagnostics) Safety and labeling standards must be met • Used medical equipment classified under the EU classification system • The healthcare provider must verify compliance with Swissmedic and ensure the device does not enter the market for resale • Used devices may face additional scrutiny during customs clearance	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity	• Used devices cannot be supplied to patients unless they are implants • Devices must be appropriately labeled in the Swiss national languages (German, French, and Italian)
Ukraine	• Import license required • (U.S.-Only) License Exception MED allows the export, reexport, and in-country transfer of EAR99 medical devices (low-tech medical products) to Russia, Belarus, and the occupied regions of Ukraine	• Registration with the State Expert Center of the Ministry of Health is required for medical devices • Meet Ukrainian safety and labeling standards • Importers must be registered at Customs as foreign trade entities • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Export Declaration or T1 • Declaration of Conformity might be required based on device type • Data Sheets and Photos required • An EORI number is needed to import goods into the EU	Ukrainian language labeling required

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
EUROPE				
United Kingdom	Equipment registration with the Medicines and Healthcare products Regulatory Agency (MHRA).	• UKCA marking required for most devices • Compliance with EU Medical Device Regulation (MDR 2017/745) • Equipment must be fully re-certified, safe and meet UK MDR 2002	• Commercial Invoice, Bill of Lading, Shipper's Export Declaration and Declaration of Conformity • All equipment must be declared via the UK CDS customs system • Used medical devices may require inspection and testing for safety compliance	
Vatican City	No special import licenses for medical devices.	• CE mark Compliance with EU Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) • Safety and labeling standards must be met • Used medical equipment classified under the EU classification system	• Importers must use the Single Administrative Document (SAD) for customs declarations • Commercial Invoice, Bill of Lading, Shipper's Export Declaration • Declaration of Conformity • An EORI number is needed to import goods into the EU	Imports are regulated by Italy under the EU system.
AFRICA				
Angola	• Import License from ARMED (Ministry of Health) • Companies must be registered with the Ministry of Industry and Trade to import	• Labels must include product ingredients, expiration dates, quantity, production batch, manufacturer/seller info, and country of origin • Proof of quality and safety, and must meet sanitary standards	Commercial invoice in Portuguese, Certificate of Origin, and potentially a batch quality control certificate. Pre-shipment inspection is not mandatory but can expedite clearance if done.	Labeling in Portuguese is mandatory.
Algeria	No importation of used and refurbished medical equipment is allowed.			
Benin	Import license.	• Used medical equipment can only be imported after registration with ABREP • Must meet the requirements outlined in the ABREP 2020 guidelines	• Invoice, Bill of Lading, inspection certificates, and attestation of origin • Power of Attorney • Free Sale Certificate • GMP inspection letter • Laboratory analysis is required for approval	
Botswana	• Import permits are required for goods entering Botswana from outside the Southern African Customs Union (SACU) • Permits must be obtained from BoMRA (Botswana Medicines Regulatory Authority)	Used medical equipment must be registered with BoMRA before importation.	• Customs duties are paid using the SAD 500 (bill of entry) form • Invoice, Bill of Lading, inspection certificates, and attestation of origin	• Goods from SACU countries enjoy duty-free access, but used equipment must comply with BoMRA regulations

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Burkina Faso	Import permit issued by ministry of commerce, industry, and handicrafts.	• All used medical equipment must be registered with the Directorate General of Pharmacy, Medicines, and Laboratories (DGPML) to ensure it meets Burkina Faso's safety, quality, and efficacy standards • Must comply with ABNORM standards	• Pre shipment inspection is required for used medical equipment with a value exceeding FCFA 1,000,000 (USD 1,565), conducted by COTECNA • On arrival, DGPML will verify invoices, and the National Laboratory of Public Health (LNSP) will perform quality control checks	Imports from WAEMU and ECOWAS countries may benefit from preferential tariff rates but must follow all regulatory steps.
Burundi	ABREMA import authorization via ASYCUDA; local accredited agent mandatory.	• Used equipment must comply with ABREMA's 2020 guidelines • Used devices must be fully reconditioned and tested before shipment. Essential parts, accessories and working materials must be included. A certification of refurbishment must accompany each unit • Devices must have labels (or manuals) with name, model, serial number, manufacture/expiry dates, manufacturer/importer details, refurbishment status and user instructions in English or Kirundi/French	• Import authorization certificate from ABREMA, commercial invoice, Packing List, Airway Bill or Bill of Lading, Certificate of Orgin, refurbishment certificate, sterilization certificate (if sterile) radiation device permit (if applicable) • Customs clearance is handled via the ASYCUDA Single Window linked to ABREMA. Most approvals occur within 1-9 days	• Used devices must have ≥60% remaining shelf life at import, unless expedited for emergencies. Pre-shipment inspection is required • All essential components must accompany equipment; devices with unavailable spare parts or manufacturer support are rejected • Refurbished equipment must meet international safety/efficacy standards. Electrical devices must match local voltage (220-240V, 50 Hz)
Cabo Verde	• Import license from the Chambers of Commerce • Commercial operator certificate for importers • Marketing Authorization from ERIS: application must follow ICH guidelines	Must comply with ERIS regulations.	• Commercial invoices, Bill of Lading, health certificates if applicable, and Certificate of Origin • Customs checks may include inspections	• Labeling must be in Portuguese • Waterproof packaging is necessary due to the tropical climate • Cabo Verde follows phytosanitary controls on wood packaging and materials like hay/straw but does not adhere to ISPM 15 standards
Cameroon	Technical import opinion required.	• Only approved organizations approved by the Ministry of Public Health can import used medical equipment • Fumigation certificate is required for used medical equipment to certify it is free from harmful germs or viruses • Quality certificate for environmental safety might be required	• The importer must submit a technical file for registration with the Direction des Médicaments et de la Pharmacie (DMP) before the equipment enters the country • SGS verification is required for customs clearance	
Central African Republic	• Import permit from the Ministry of Public Health • Certificate of Free Sale (CFS) for medical devices	• Must be registered and labeled with manufacturer information • GMP certificate required. Pre-shipment Inspection (PVoC) mandatory	Ectn required. Additional taxes may apply in Bangui.	• Zero value invoices not accepted • Bureaucratic procedures and potential corruption can cause delays

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Chad	• Import permits from the Ministry of Public Health • Import permits for pharmaceuticals and veterinary medicines required from relevant ministries	• Certain devices may require a Certificate of Free Sale (CFS) and a Certificate of Good Manufacturing Practice (GMP) • Special labeling and registration for medical products under the Ministry of Health	Commercial invoice, Certificate of Origin, packing list, Bill of Lading/Air Waybill, and ECTN reference required for customs clearance.	
Comoros	• Import license required • Approval from the Ministry of Health is required for medical devices • Certain devices may require special permits	• Must comply with health regulations • Specific labeling in French may be required • Health certifications • CE marking may be necessary	• Commercial Invoice, Certificate of Origin, Packing List, Bill of Lading/ Air Waybill, and ECTN may be required • Allow 4 to 6 weeks processing • Documents in French preferred	• Bureaucratic delays • Documentation requirements may vary
Democratic Republic of the Congo	• Import license required for medical equipment • License must be obtained through an authorized commercial bank and validated by BIVAC	• No specific regulations for used medical equipment • Must meet health and safety standards • Used equipment should resist tropical conditions (heat, moisture, pests) • Equipment must comply with local infrastructure and maintenance capabilities • Post-market oversight remains a challenge, with a focus on pre-market approval	• Pre shipment inspection by BIVAC for equipment valued over $2,500 • Certification of validation issued after inspection	• Medical equipment is exempt from VAT • Medical devices donated or imported for humanitarian purposes are exempt from VAT • No specific packing regulations, but international packing norms (IATA, ICAO) must be followed
Republic of the Congo	No specific import permits required for used medical equipment	No special labeling or marking requirements.	• Bill of Lading and invoice required. • Processing fee of 20% to 60% of CIF cost applies	French labeling required (though not strictly enforced).
Djibouti	Import permits are required.	• Must comply with GHTF/ IMDRF regulations, ensuring safety and performance standards • Certificates of Origin and other relevant technical documents may be necessary	• Commercial invoices must be detailed and translated into French, including currency, unit value, and HTS code • Shipment inspections (BIVAC) are required for items over $2500	
Egypt	No importation of used and refurbished medical equipment is allowed.			

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COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Equatorial Guinea	Type approval from ORTEL is required for all imported used medical equipment.	• Equipment must meet technical, safety, and environmental standards • Equipment must be evaluated for safety, electromagnetic compatibility, and environmental impact • Compliance with international health standards, such as WHO guidelines, is mandatory • A conformity assessment must be conducted to ensure compliance with technical regulations	• Invoices, Packing Lists, and the ORTEL type approval certificate • Customs will require additional documentation, including the conformity assessment report • Ensure that the equipment passes inspection for functionality and safety before customs clearance	• A type approval certificate is required for used medical equipment to verify that it meets Equatorial Guinea's standards • All used medical equipment must undergo testing and certification before importation • Expert advice may be needed to navigate the complex regulatory framework • Importers should be aware of restrictions on certain types of medical equipment based on safety concerns
Eritrea	Import permit from the Ministry of Health required.	• Medical equipment must be registered with the Ministry of Health • Certificate of Free Sale (CFS) and Health Certificate required for medical devices	• Customs clears based on invoices, CFS, and Health Certificate • Inspection may be required.	
Eswatini	• Import permit required • Issued by the Ministry of Finance and Ministry of Health	• Equipment must meet Eswatini's health and safety regulations • Country of origin labeling is required	• Bill of entry, supplier invoices, and import permit must be submitted • Customs clearance includes a health inspection by the Ministry of Health	Non compliance may result in fines, penalties, and seizure of goods.
Ethiopia	Import license required.	• Used medical equipment must comply with EFDA's registration requirements for medical devices • Used medical devices must be cleaned, disinfected, sterilized (as appropriate), reconditioned and tested • Documentation must include product safety, performance, and technical specifications • The EFDA assesses the risk associated with each device	• Importers must submit a Bill of Lading, Certificate of Origin, and commercial invoices • A certificate from EFDA confirming product registration is required • Customs clearance is based on documentation and EFDA approval	Service fees for medical device registration: 350 Birr for screening, 1300 Birr for evaluation.
Gabon		• Regulated under PROGEC (Gabonese Conformity Assessment Program) • Must comply with AGANOR standards for safety and performance • Medical equipment must meet international or national standards (e.g., ISO) before import	• Bill of Lading and invoice are mandatory • Certificate of Conformity (CoC) required • Goods must undergo a conformity assessment before shipment	French labeling required (though not strictly enforced).

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COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Ghana	• Importer must register used medical equipment with Ghana FDA • Import permit valid for one year	• Equipment must meet safety and performance standards (ISO, IEC) • Used equipment must be fully operational and meet standard performance requirements • Equipment must be documented (source, repair history and service records) • Labeling: Product name, expiry date, country of origin, and batch/lot number • The FDA must be notified of any performance or safety issues • Used equipment must be accompanied by a user manual, maintenance records, training manual, and a spare parts guarantee • Equipment that has been recalled or flagged for hazards is not accepted • Local agent required for non resident importers	• Submit Import Declaration Form • Obtain Tax Clearance • Submit Bill of Entry via ICUMS • Inspection by FDA and Customs • Verification that the equipment is fully operational and meets required standards • Required documents: Service and maintenance history, installation manual, user manual and spare parts guarantee	
Guinea	Import authorization (DDI) required from the ministry of commerce for imports exceeding 12 million gnf (approx. usd 1,250).	No specific labeling or marking requirements for used medical equipment.	Use Guichet Unique portal for the importation process.	Corruption is a concern in customs clearance and delays may occur.
Guinea-Bissau	No specific permit required for used medical equipment.	• Used medical equipment must meet basic safety and hygiene standards • Used medical equipment cannot be sold, lent, or otherwise disposed of during its stay	• Original Bill of Lading/Air Waybill (original) • Documents must be submitted to the Destination Agent at least 8 days prior to the shipment's arrival • Customs clearance typically takes 10 to 30 days	

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Ivory Coast (Côte d'Ivoire)	Import license may be required for certain types of medical devices.	• Used medical equipment must be registered or approved with the Direction de la Pharmacie, du Médicament et des Laboratoires (DPML) • Medical equipment must meet Ivoirian health and safety standards • Must be labeled with the country of origin (e.g., "MADE IN THE U.S.A.") • Equipment must meet European electrical standards and metric system requirements • CE Certification required for medical devices and other specified products • Expiration and manufacture dates must be clearly visible for medical equipment to avoid health risks	• Commercial Invoice, Certificate of Origin, Packing List, and Pro-Forma Invoice (if applicable) • If the FOB value exceeds 1 million CFA (approx. $1,600), a pre-shipment inspection is required to verify the value and ensure compliance with import declarations • The inspection is conducted by an authorized company (fee: 0.75% of the FOB value)	French language requirement for manuals, software, and symbols.
Kenya	Import permits are not required.	• Used medical equipment must be inspected under the PVoC program to ensure it meets required health and safety standards • The equipment must also comply with all Kenya Bureau of Standards (KEBS) regulations • Equipment may need to be tested to ensure it is safe for use in medical settings	• Certificate of Conformity (CoC) through the pre-shipment Verification of Conformity (PVoC) process • All customs documentation must be submitted via the Kenya National TradeNet System (KESWS) • Customs may require a detailed inventory and/or an inspection report	
Liberia	LMHRA requires import permits.	• Registration with the Liberia Medicines and Health Products Regulatory Authority (LMHRA) is mandatory for medical products • MOCI requires proper labeling with details such as expiration dates, manufacture dates, and origin • LMHRA may suspend registration if the device fails to meet required Good Manufacturing Practices (GMP)	• Used medical equipment must pass clearance by the Liberia Revenue Authority (LRA) • Electronic filing and payments via LITAS system are required for customs procedures • Pre-shipment inspection through BIVAC may apply for goods above US $3,500	Used medical equipment may be subject to additional quality control checks by the LMHRA.

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Libya	No specific import permits required for used medical equipment.	• Used medical equipment must comply with Libyan health and safety standards, or international standards if no Libyan standards are available • Conformity assessment must be conducted before shipping • Products are assessed by Bureau Veritas for conformity to Libyan regulations under the ARN 2020/68 list	• Bureau Veritas inspects the used medical equipment before shipment to verify conformity • Inspection includes reviewing documents, physical inspection, and potentially laboratory testing of equipment if Libyan standards do not exist • Certificate of Inspection (CoI) • Letter of Credit (L/C) Inspection Report • If issues are found, a Non-Conformity Report (NCR) is issued	
Madagascar	Not generally required for used medical equipment unless specifically classified.	Used medical equipment must comply with Malagasy or international standards.	Must include unit value, number of units, and currency. Packing List: • Certificate of Origin • BSC (Bordereau de Suivi des Cargaisons), to be filled out online • HTS Code must be included for proper product classification	
Mali	Import license may be required.	• Importers must comply with the Directorate of Pharmacies and Medicines (DPM) • All used medical equipment must meet health safety standards as overseen by the National Health Laboratory (LNS) • Risk-based Post-Marketing Surveillance (RBPMS) is applied to monitor the quality of medicines and medical devices	• Commercial invoice, Packing List and Certificate of Origin • Cargo tracking document (BSC) • Inspection and physical examination may be required to ensure compliance with health and safety standards	Ongoing efforts aim to establish a stronger regulatory framework for used medical equipment.
Mauritania	Import license required.	Sanitary certificate may be required, depending on the nature of the medical equipment.	• Pre-shipment inspection by SGS (Société Générale de Surveillance) is required • Certificate of Inspection (issued by SGS) • Commercial invoice, Bill of Lading, Certificate of Origin and SGS certificate	

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Mauritius	• Import permits may be required for used medical equipment under certain regulations • Import permits or health certifications may be necessary for second hand medical equipment	• Used medical equipment must meet Mauritian health and safety standards • May be subject to inspection to ensure compliance with local medical regulations. Recertification and disinfection of used medical equipment might be required	• Bill of Lading/Airway Bill • Bill of Entry, Invoice, Packing List • Certificate of Origin (if applicable) • Insurance certificate (if applicable) • Inspection and clearance by Mauritian authorities	
Morocco	No importation of used and refurbished medical equipment is allowed.			
Mozambique	Import license required.	• All medical equipment importers must be registered as foreign trade operator with the Ministry of Health • Used medical equipment must comply with Mozambican health and safety standards • Equipment may need to be recertified for safety and effectiveness before being allowed into the country. Pre-shipment inspections are mandatory for all medical imports. • Must comply with the Mozambique Conformity Assessment Programme (CAP)	• Certificate of Conformity (CoC) • Bill of Lading, Commercial Invoice, and Certificate of Conformity • Inspection and approval by the National Institute of Standards and Quality (INNOQ) may be required	Labeling must be in Portuguese.
Namibia	Import permits may be required.	• Importers must be licensed by the Ministry of Industry and Trade • Used medical equipment must comply with Namibian health and safety standards • Equipment must be in working condition	• Import declaration is required • Inspection on arrival • Conformity checks are mandatory • Compliance with Conformity Assessment Program (CAP) • Certificate of Conformity	
Niger	Import license required.	• Importers must be licensed by the Ministry of Health for medical devices • Compliance with NAFDAC regulations for registration	• Preliminary Import Declaration required for goods ≥ CFA 1 million • COTECNA inspection required for goods ≥ CFA 2 million	Labeling in French required (origin, expiration, usage).

COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
AFRICA				
Nigeria	Import license required.	• Must meet NAFDAC registration requirements • Must meet health and safety standards • Must comply with international standards • Local Authorized Representative is required for foreign manufacturers	• Pre-shipment inspection required • Shippers must ensure IDR number is quoted on the manifest • Name, country of origin, batch number and expiration date • Bill of Lading, commercial invoice, Certificate of Origin • Goods are inspected on arrival by Nigeria Customs Service (NCS)	Local insurance required for all imported goods.
Rwanda	Import license required.	• Proof of compliance to international standards required (ISO, CE, IEC) • Equipment must meet labeling requirements (Kinyarwanda, English and French) • Importer must submit clinical trial approval if applicable for investigational use	• Submit proforma invoice and other import documents • Certificate of refurbishment • Certificate of Analysis or Certificates of Conformity • Goods must undergo physical inspection upon arrival or at the importer's premises • Submit goods arrival notice to the Rwanda Standards Board for verification	
Senegal	Import permits may be required.	CE certification required for certain medical devices.	• Pre-shipment inspection (PSI) required by Cotecna for goods valued at FCFA 3 million and higher • Preliminary Declaration of Import (DPI) for goods over FCFA 1,000,000 • Invoice, Certificate of Origin, Packing List and insurance certificate	Labeling must be in French; "Vente Au Senegal" marking for sale in Senegal.
South Africa	Import permit required for used medical equipment from ITAC.	• Registration with SARS • Compliance with South African Bureau of Standards (SABS) required • CE marking may be needed for certain devices • Equipment must meet health, safety, and environmental standards	Bill of Lading, Commercial Invoice, Packing List, insurance certificate and SAD form.	
Sudan	• (U.S.-Only) Export licensing may be required by the BIS for exports from the U.S. • Import permits may be required	• Importers must be registered with Sudan Customs and the Ministry of Interior to import goods into the country • Compliance with local and international standards, such as ISO and CE marking, may be required for certain types of medical devices • Medical equipment must meet Sudan's health and environmental regulations	• Commercial invoice, Bill of Lading, Packing List, Certificate of Origin, and insurance certificate • Letters of credit (LCs) are required for transaction in Sudan	

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AFRICA				
Tanzania	Import permits required from TMDA.	• Importers must apply for an importation permit through TMDA's online portal • Proforma invoice required • Devices must be labeled according to TMDA-approved specifications	• A licensed Licensed Clearing and Forwarding Agent (CFA) must be appointed • Invoices, permits and transport documents must be lodged 7 days before arrival through TANCIS system	Labeling in English/Kiswahili.
Togo	Import permit required from the Ministry of Agriculture, animal, and fish production.	• Used medical equipment must be registered and have marketing authorization prior to importation • Medical equipment must comply with labeling and health standards • Labeling must include the manufacturer's name and address	Certificate of free sale (CFS) and GMP certificate.	
Uganda	Import permit required.	• All medical devices, including used ones, must be registered in Uganda • Medical devices must comply with National Drug Authority (NDA) requirements • Labels must include the manufacturer's name, address, and safety information	• Bill of Lading, commercial invoice, health certificate (if applicable) and import certificate • Certificate of Free Sale (CFS) and GMP certificate • Single Administrative Document (SAD)	
Zambia	Import permit may be required.	• Used medical equipment must comply with Zambia Medicines Regulatory Authority (ZAMRA) regulations • All medical equipment, including used items, must be registered before importation • Equipment must be inspected and certified as safe for use	• Declaration made through the ASYCUDA system • Commercial invoice, Bill of Lading, import declaration, and ZAMRA certification (if required) • The Zambia Revenue Authority (ZRA) may request additional inspection or documentation • A clearing agent may be required for consignments with a CIF value above USD 2,000	
Zimbabwe	Import permit from the Medicines Control Authority of Zimbabwe (MCAZ).	Zimbabwe lacks a comprehensive regulatory framework for medical devices.	Bill of Lading, commercial invoice, Packing List, insurance certificate	

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COUNTRY INFORMATION	LICENSING/PERMITS	REGULATIONS	CUSTOMS PROCEDURES	MISCELLANEOUS NOTES
OCEANIA				
Australia	• Importers may not need an import license but could require permits for certain types used medical equipment • Permits might be necessary depending on the type and condition of the equipment	• All medical devices must comply with Australian standards for safety, quality, and efficacy • Equipment must be accurately labeled and include the country of origin	• Used medical equipment must be accurately declared on customs documents • Commercial invoice, Bill of Lading, and other relevant documents	Used medical equipment is subject to additional scrutiny by the Therapeutic Goods Administration (TGA).
Fiji	Import permits may be required.	• Used medical equipment must comply with the Medicinal Products Act 2011 • Must be sourced from reputable suppliers and meet quality standards • Equipment must be cleared for biosecurity risks if applicable	Commercial invoice, Bill of Lading, and other relevant documents.	
Micronesia	There are no specific requirements for importing medical items into Micronesia.			
New Zealand	No specific import permits required for used medical equipment.	• Medical devices must be notified to the WAND database within 30 days of becoming a sponsor • A New Zealand Sponsor is required for importation • Medical devices must meet safety, quality, and efficacy standards under the Medicines Act 1981 and the Medicines (Database of Medical Devices) Regulations 2003	Commercial invoice, Bill of Lading, and other relevant documents.	
Palau	There are no specific requirements for importing medical items into Palau.			
Papua New Guinea	Import of used medical equipment requires a permit or license.	• Used medical equipment must comply with packaging and labeling requirements under the Packaging Act • Must include the approved brand or packer's details	• Bill of Lading, Commercial Invoice, Packing List/ Inventory List, Customs Valuation Declaration/ Customs Entry • Import declaration must be submitted via Direct Trader Input (DTI) system by licensed agent	Goods may be subject to inspection by customs at any point.

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Spain

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Vatican City (same laws as Italy)

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Angola

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Algeria

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https://www.bomra.co.bw/medical-devices/

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http://www.douanes.bf/sydoniabf/index.jsf

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Republic of Congo

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Djibouti

https://www.dgra.de/media/pdf/studium/masterthesis/master_samadi_f.pdf

https://www.shiprrexp.com/global_shipping_documents/Djibouti.html

https://app.croneri.co.uk/countries/djibouti

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Ivory Coast (Cote d'Ivoire)

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https://infotradekenya.go.ke/procedure/320?l=sw

Liberia

https://www.trade.gov/country-commercial-guides/liberia-customs-regulations

Libya

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Niger

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https://rwandatrade.rw/procedure/877/step/4562?l=en

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https://www.certvalue.com/ce-certification-in-senegal/#:~:text=Certvalue%20is%20a%20professional%20multi,products%20of%20your%20manufacturing%20operation.

https://www.douanes.sn/

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https://www.nda.or.ug/medical-devices/#1603100423514-243dfaab-82dd

Zambia

https://www.trade.gov/country-commercial-guides/zambia-customs-regulations

https://www.zra.org.zm/importation-of-goods/

Zimbabwe

https://www.trade.gov/country-commercial-guides/zimbabwe-customs-regulations

OCEANIA

Australia

https://www.trade.gov/country-commercial-guides/australia-customs-regulations

https://www.abf.gov.au/importing-exporting-and-manufacturing/importing/how-to-import/import-declaration

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https://www.tga.gov.au/resources/resource/reference-material/importing-and-supplying-medical-devices#:~:text=Does%20the%20TGA%20regulate%20medical,goods%20in%20section%203%20include:

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https://www.trade.gov/country-commercial-guides/fiji-customs-regulations

https://baronworldwide.com/wp-content/uploads/2019/02/fiji.pdf

https://www.health.gov.fj/fiji-mra/#:~:text=Provisionally%20Authorised%20Medicinal%20Products%20Register,in%20Australia%20or%20New%20Zealand.&text=Once%20logged%20in%2C%20you%20must,company%20details%2C%20and%20license%20documents.

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Note:

The import and export regulations, licensing requirements, and tariffs outlined in this document are subject to change and may vary by jurisdiction, equipment type, and specific circumstances. While we strive to keep this information current, we strongly recommend consulting the appropriate governmental authorities or official trade resources—such as each country's Ministry of Health, Customs Authority, or Trade Ministry—for the most up-to-date and accurate information.

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