

whitepaper

This Paper:

This paper explores the risks associated with shipping medical devices in non-compliant packaging, the regulatory requirements for returns, and the benefits of using compliant 95 kPa return bags.

With certified packaging, OEMs can mitigate the dangers of biohazard exposure and ensure compliance with regulatory standards, protecting their business and reputation.



Medical Device Returns:

The Critical Need for Compliant 95 kPa Packaging to Protect OEMs

The Issue Section:

Non-compliant packaging for returned medical devices exposes OEMs to significant risks. Regulatory bodies such as the FDA and DOT impose strict packaging requirements to ensure safe transport, but healthcare facilities often overlook the importance of compliance during returns. This can result in biohazard exposure, contamination, regulatory violations, and damage to an OEM's reputation. When shipping fails, the responsibility lies with the OEM—not the shipper or healthcare facility.

Key points:

- OEMs face hefty legal and regulatory consequences if devices are returned in non-compliant packaging.
- Non-compliant returns increase the risk of contamination and biohazard exposure for logistics and handling personnel.
- The Department of Transportation (DOT) & International Air Transport Association (IATA) mandate the use of certified 95 kPa bags for the safe return of medical devices.

The Problem

Two global healthcare OEMs recently faced critical issues with non-compliant medical device returns. A used medical device containing biological fluids was shipped in inadequate packaging, leading to potential exposure and contamination at every stage of its journey—from healthcare facility to logistics carriers, and ultimately to the OEM. When the device arrived damaged, personnel were unknowingly exposed to hazardous substances.

The Outcome

Had the healthcare facility used a compliant 95 kPa return bag, the risk of exposure and contamination would have been significantly reduced. This compliant packaging would have provided a secure, tamper-evident barrier and protected all individuals involved in the process.

Why 95 kPa Bags Are Essential for OEMs:

95 kPa bags are designed to meet the stringent requirements of the FDA, DOT, and IATA for shipping medical devices with potential biological contamination.

These bags offer:

- Leak-proof, tamper-evident seals to prevent contamination
- Pressure-tested durability to withstand transit conditions
- Triple-layer packaging that protects against biohazard exposure
- Clear labeling for compliance with all regulatory standards

By specifying 95 kPa bags, OEMs can ensure the safe return of medical devices, protect personnel, and meet regulatory requirements.

Medical device OEMs must adopt certified 95 kPa bags to protect their team, ensure compliance, and reduce liability.



Ensuring Compliance and Safety with 95 kPa Bags:

OEMs are responsible for ensuring compliance in all stages of the medical device lifecycle, including returns. Certified 95 kPa return bags mitigate the risk of contamination and liability, ensuring the safe transport of devices.

Vonco offers USA-made, TEN-E tested 95 kPa biohazard transport bags that meet regulatory standards for both air and ground transport. Protect your team and your reputation by specifying compliant return packaging for all medical device returns.

Contact Us

Contact Vonco to learn more about our certified 95 kPa packaging solutions.

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