Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

Material Identification through FTIR Spectroscopy: Ensuring Safety and Compliance in Medical Device Development

25 August 2025

Material identification is a cornerstone of medical device development and quality control. At Medistri, our FTIR (Fourier Transform Infrared) spectroscopy services provide manufacturers with precise, traceable material characterization to support regulatory compliance and patient safety throughout the product lifecycle.

Whether you are validating raw materials, investigating unknown contaminants, or characterizing device components, our FTIR analysis delivers the accuracy and compliance your projects demand.

Understanding FTIR Spectroscopy
FTIR spectroscopy identifies materials by measuring how they absorb infrared light. Each material produces a unique spectral "fingerprint," enabling reliable confirmation of polymers, additives, contaminants, and residual solvents. This makes FTIR a powerful tool in medical device development, where understanding material composition is critical to both safety and compliance.

At Medistri, our Agilent Cary 630-FTIR system with ATR diamond accessories and certified reference databases ensures comprehensive coverage across diverse applications, including:

- Identification of polymers and elastomers in device components and packaging
- Detection of additives and processing aids such as stabilizers, lubricants, and plasticizers
- Characterization of contaminants or foreign matter, including particles and residues
- Analysis of residual solvents that may affect safety and performance

Regulatory Standards & Compliance
Our FTIR protocols are aligned with international standards, ensuring results are accepted by regulatory authorities worldwide. We operate under ISO/IEC 17025 accreditation, following the requirements of ISO 10993 for chemical characterization and toxicological risk assessment.

Key standards include:

- ISO/IEC 17025 – competence and traceability of results
- ISO 10993-18 – chemical characterization of device materials
- ISO 10993-17 – toxicological risk assessment (TRA) using chemical data
- USP <854> – mid-infrared spectroscopy
- USP <661.1>, <661.2>, <1661> – plastic materials and packaging systems

This comprehensive framework supports faster regulatory approvals and reduces compliance risks.

Database Matching & Identification
Reliable identification requires robust database matching. Medistri's certified spectral libraries provide broad coverage of relevant material classes, enabling confident identification across a wide spectrum of applications.

Our reference databases include:

- Polymers and additives, including medical-grade materials
- Organic compounds, solvents, and processing chemicals
- Pharmaceuticals and excipients
- Foreign powders and particles, including suspected contaminants

This extensive coverage ensures reliable results in both routine quality control and complex investigations.

Quality Assurance & Validation
Every FTIR analysis is supported by a rigorous quality assurance process. System performance is verified before each session, and certified reference standards such as polystyrene, sucrose, and methanol are routinely analyzed to confirm accuracy.

Additional measures include:

- Method validation and recovery studies for challenging sample types
- Quantitative correlation scoring with acceptance criteria of ≥0.90

All of these procedures are performed under ISO 17025 accreditation, ensuring traceable, reproducible, and regulatory-compliant results.

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Optimized Sample Preparation
Sample preparation is a critical step for obtaining reliable spectra. Medistri applies standardized protocols adapted to the type of material under analysis. This ensures clean, representative, and interference-free data.

Our preparation approaches include:
- Sectioning and cleaning of solid materials to avoid contamination
- Direct analysis or controlled evaporation for liquids and solvents
- Even distribution of powders under ATR pressure
- Specialized handling of trace contaminants present in very small amounts

Each preparation step is documented and traceable, maintaining full chain of custody in line with ISO 17025 requirements.

Partnering with Medistri
By partnering with Medistri, manufacturers benefit from rigorous analytical methods, rapid turnaround times, and expert interpretation of results. Our team provides comprehensive reports suitable for regulatory submissions and can develop tailored methods for specialized applications.

Key advantages of working with us include:
- Full traceability under ISO/IEC 17025 accreditation
- Rapid response to support critical decision-making
- Expert guidance for regulatory submissions
- Custom method development for complex material challenges

To learn more about our FTIR material identification services, visit our website here or contact our dedicated team at contact@medistri.com.

— The Medistri Team

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Real-World Applications
FTIR analysis provides value at multiple stages of the medical device lifecycle. It is widely used to qualify incoming raw materials, investigate unexpected residues during manufacturing, and characterize degradation products or contaminants in returned devices.

It also provides chemical characterization data required for regulatory submissions, helping manufacturers accelerate approval timelines and safeguard patient safety.

Driving Material Safety Through Reliable Analysis
In today's regulated environment, reliable material identification is essential for device safety, regulatory compliance, and patient protection. Medistri's FTIR services deliver the analytical foundation required for successful market approval and long-term product performance.