eurofins | Medical Device Testing



# Extractables, Leachables & Chemical Characterization Testing

Chemical characterization is the first step in the workflow used to establish the biological safety of medical devices, as required by ISO 10993.

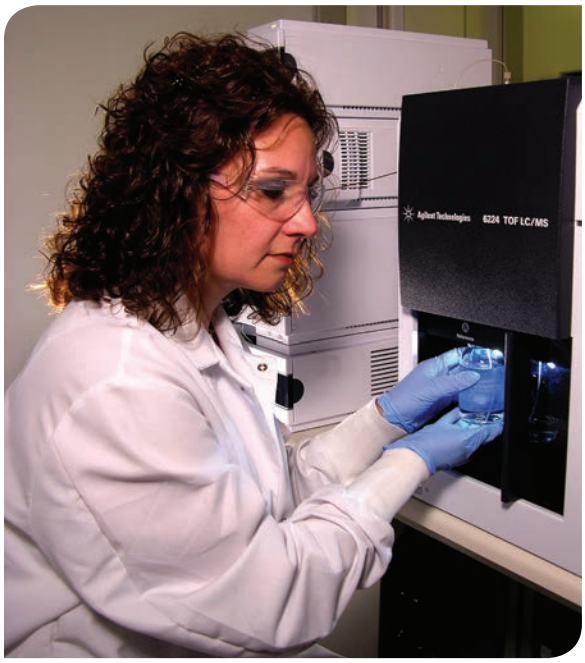
Many compounds are intentionally added during the manufacture of a device, including colorants, plasticizers, impact modifiers, and processing aids. Others may be picked up inadvertently during processing or result from a degradation reaction during sterilization or storage.

Extractables and Leachables (E&L) testing is performed to determine what chemical compounds are in your medical device, that could raise potential toxicity concerns.

Eurofins Medical Device Testing has 30 years of experience in chemical characterization of medical devices, with 80 scientists making up our E&L team. Our state-of-the-art laboratories are ISO 17025 accredited and equipped with over 500 HPLCs and GCs to accurately identify what compounds may leach from your product during use. Our team of experts will help guide you through the selection of appropriate solvents and extraction conditions when designing a test protocol.

### Choose Eurofins Medical Device Testing to help you:

- Determine the most relevant testing conditions for your product and write your protocol
- Execute your study within a GMP/GLP/ISO 17025 compliant quality system
- Identify extractable compounds using our proprietary spectral database of over 1,500 non-volatile compounds
- Assess the toxicological risk of identified compounds according to ISO 10993-17 and provide a report that is ready for regulatory submission




Important phases in your product development lifecycle that may require E&L assessments include:

- Developing new product design concepts
- Performing verification testing for your design history file
- Changing raw material suppliers
- Implementing design or manufacturing process changes

### Testing Available

Our extractables studies can be designed per guidances such as ISO 10993 Part 18, USP <1663> and <1664>, as well as FDA/CDRH, EMEA and PQRI documents.

- Validation in compliance with ISO 10993-18
- Extraction Techniques (for exaggerated, exhaustive, and simulated-use extractions):
  - Reflux
  - Soxhlet
  - Sonication
  - Incubation/maceration in controlled temperature conditions (with agitation if needed)

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## Testing Available (cont.)

- Analysis Techniques:
  - Fingerprinting by GC-FID/MS
  - Semi-quantitative screening for both volatile and semi-volatile organic compounds by GC/MS and GC/MS Headspace
  - Semi-quantitative screening for non-volatile organic compounds by LC/MS
  - Quantitative analysis for metals by ICP/OES or ICP/MS
  - Gravimetric (NVR) determination of extractables
  - FTIR TOC
  - pH
  - Conductivity
- Method establishment for novel extraction matrices
- Toxicological risk assessment

## Instrumentation

- Agilent LC/MS TOF and QTOF
- Agilent/Waters HPLC/UHPLC – including UV/Vis, RI, Fluorescence, ELSD, CAD, and Conductivity detectors
- Agilent GC/MS – both headspace and direct injection sample introduction
- Agilent GC/FID/TCD – both headspace and direct injection sample introduction
- Agilent ICP/MS and ICP/OES
- Thermo Scientific iCAP ICP-OES
- Thermo Scientific LC/MS/MS
- Perkin Elmer ICP-OES
- Perkin Elmer 350 ATD Thermal Desorber
- Bruker Avance 3 (500 MHz) Liquid NMR
- Bruker Avance 3 (400 MHz) Liquid NMR

## Additional Complimentary Services

- Method Development & Validation
- Stability for Leachables
- Toxicological Risk Assessments
- Biocompatibility Testing