

STERILIZATION ACCREDITATION

What is MedAccred?

MedAccred is an industry-managed supply chain oversight program which identifies and verifies compliance to critical manufacturing process requirements. Leveraging their considerable collective experience, subject matter experts have collaborated to create a deep dive technical audit system which provides exceptional supply chain oversight.

Why MedAccred?

- To improve the quality of products and most importantly patient safety
- The need to reach through the sub-tiers in the complex global critical process supply chain
- To improve the reliability of the supply chain

MedAccred Sterilization Accreditation

The MedAccred Sterilization audit assesses a supplier's ability to consistently manufacture components that comply to applicable technical specifications and customer requirements. A MedAccred audit is conducted by a subject matter expert and verifies that an accredited supplier has the:

- Process Capability
- Applicable Equipment
- Controls and Monitors
- Qualified personnel
- Process validation
- Sub-tier controls

Sterilization Audit Scopes

- Ethylene Oxide
- Radiation (Gamma & E-Beam)

Benefits to Participation

- Reduces number of redundant customer audits
- Improves process capability
- Improves Patient Safety

MedAccred Subscribers

- Baxter Healthcare
- BD
- Boston Scientific
- Fdwards Lifesciences
- Johnson & Johnson
- Medtronic
- Philips
- Roche Diagnostics
- Stryker



Subscribers fund MedAccred, determine audit criteria, select auditors, have full access to audit findings, and determine who is granted MedAccred Accreditation.

Audit Quick Facts:

- Audit Length: 2 days
- Audit Frequency: Annual
- Audit Prerequisites: ISO 13485
- Other Available MedAccred Accreditations: Cable and Harness, Heat Treating, Plastics Injection Molding, Plastics Extrusion, Plastics Mechanical Assembly, Printed Board (Bare Board), Printed Circuit Board Assembly (PCBA), Sterile Device Packaging, Welding

To Schedule an Audit or Learn More: www.MedAccred.org

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