



IQOQ Validation Services

Installation Qualification and Operational Qualification

Accelerate your product commercialization by utilizing IQOQ Services from STERIS.

A qualification process can be time consuming and often requires specialized equipment and expertise. By working with our global team of technical specialists, you gain not only validation compliance directly from the OEM, but you also benefit from faster time to market.

Whether your equipment is newly installed or being relocated, IQOQ is a key element of your overall validation program. Our service ensures compliance with industry and GMP requirements and includes extensive documentation, including all test procedures, complete equipment drawings, parts lists and more. Testing is performed at your facility under operational conditions to verify that your equipment has been properly installed and works as designed.

Comprehensive Qualification Services

The IQOQ Service begins with an equipment-specific comprehensive document that is then executed on-site by a STERIS service technician. The service includes three (3) main focus areas - General Information, IQ and OQ.

General Information

- Outline of test plan, including instructions and identification of testing personnel
- Prerequisite Information

Installation Qualification (IQ)

- Verify the physical characteristics of the unit (mechanical and electrical components)
- Confirm proper equipment installation
- A fully-traceable calibration

Operational Qualification (OQ)

- Set of rigorous tests to validate operation of the equipment - including cycle verification, inputs, outputs, alarms and aborts testing, and more

Following completion of this comprehensive service, you will receive:

1. Signed IQ and OQ certificates of completion
2. The final IQOQ document
3. Executed IQOQ test procedure with corresponding print tapes for your review and approval
4. Calibration report and equipment specific technical data (specifications, schematics, recommended spare parts list)

Meet your compliance and regulatory requirements with our complete qualification program.

