Installation Qualification

Your quality solution to support ISO 13485
Installation Qualification (IQ)

Installation Qualification (IQ) verifies that the equipment being qualified, as well as its sub-systems and any ancillary systems, have been delivered, installed and configured in accordance with the manufacturer’s specifications.

As the equipment manufacturer, GF Machining Solutions is uniquely able to provide a completed IQ protocol that is executed immediately during the installation of the machine—saving both time and cost. The IQ protocol used by GF Machining Solutions has been developed by us in close collaboration with some of our most important medical customers.

As part of the documentation needed for compliance with 21 CRF 820, or ISO 13485, this document establishes proof that critical connections to utilities, and status of the equipment, are meeting GF Machining Solutions instructions.

For manufacturers involved in the medical device or pharmaceutical industries, product quality is paramount and having the right documentation for all manufacturing equipment is critical. Creating and executing qualification documents that meet the legal requirements of ISO 13485 takes both time and resources.

It meets the recommendations found in G@MP 5, and has been used without major changes by device manufacturers who are ISO 13485 certified. The completed IQ protocol supplied will help support your quality department in efficiently integrating GF Machining Solutions’ installed equipment into your quality system.