

Compliance Service

MGI directly provides professional service for the identification of instruments

- **Stable quality assurance**

Compliance certificate reduces repair frequency and instrument downtime, provides corresponding quality reports and ensure superior data quality and instrument performance.

- **Convenient qualification certification**

You can select this service at any time to add qualification to the instrument.

- **Flexible purchasing plan**

The gold service plan of MGI includes compliance service once a year; Purchase this service optionally.



Compliance service provided by MGI



IQ

Installation qualification

Provide documentary evidence that the equipment has been delivered and installed correctly. IQ usually needs to be performed during initial installation, laboratory relocation or major transformation in the laboratory.



OQ

Operational qualification

Verify the overall function and usability of the instrument whether comply with the specifications of original manufacturer. OQ could be performed in software upgrade, preventative maintenance or any other requirement scenario.



PQ or IPV

Performance qualification (PQ) or instrument performance verification (IPV)

Ensure the accuracy and precision of the instrument by comparing operating parameters to predetermined criteria. MGI suggests performing PQ after repairing or replacing some modules that are essential to optimize the performance of the instrument.

Compliance certification service	Service description	Recommended interval time	Service scenario
Installation Compliance (IQ)	Providing documents to prove that delivery and installation of the instrument comply with specifications and safety regulations of MGI	a) At initial installation b) After instrument relocation and subsequent reinstallation	1) Before first-time use 2) After a general change in the laboratory environment. (e.g., renovation, construction, power outage) 3) With major system upgrades
Operation Compliance (OQ)	Verify the equipment functions correctly. Especially ensure specifications are examined and quantified based on manufacturing guidelines	a) After reactive service, software upgrade, or preventive maintenance. b) Periodically operated according to lab standard operating procedures (SOP)	1) Before starting a major study or experiment, guarantee to meet the manufacturer's operating specifications. 2) IQ is usually attached to test the instrument's baseline level
Performance Compliance (PQ or IPV)	After major repair or replacement of the instrument. Ensure the accuracy and precision of the instrument by comparing operating parameters to predetermined criteria	a) After any major repair b) Periodically operated according to lab standard operating procedures (SOP)	1) After maintaining, replacing or upgrading the selected module 2) One time OQ is usually attached to identify instrument system performance

The current product matrix that we have

• IVD Instrument

	IQ/OQ/PQ	OQ/PQ
Initial installation	✓	
Required after Installation		✓
After relocation	✓	

	Initial installation/After relocation	Required after Installation
Certified/regulated customer	IQ/OQ/PQ	OQ/PQ
After key parts being replaced	IQ/OQ/PQ	OQ/PQ

• Automatic equipment-IVD

Product name	Product number
MGISP100B-IQ/OQ/PQ	980-001124-00
MGISP100B-OQ/PQ	980-001658-00
MGISP100-IQ/OQ/PQ	980-000964-00
MGISP100-OQ/PQ	980-001657-00
MGISP960-IQ/OQPQ	980-000965-00
MGISP960-OQ/PQ	980-001654-00
MGISP-NE384-IQ/OQ/PQ	980-001661-00
MGISP-NE384-OQ/PQ	980-001662-00
MGISTP3000-IQ/OQ/PQ	980-001648-00
MGISTP3000-OQ/PQ	980-001650-00
MGISTP7000-IQ/OQ/PQ	980-001651-00
MGISTP7000-OQ/PQ	980-001653-00

• Sequencer-IVD

Product name	Product number
MGISEQ200 (Config 1) -IQ/OQ/PQ	980-000955-00
MGISEQ200 (Config 1) -OQ/PQ	980-001640-00
MGISEQ200 (Config 2) -IQ/OQ/PQ	980-001151-00
MGISEQ200 (Config 2) -OQ/PQ	980-001641-00
MGISEQ2000-IQ/OQ/PQ	980-000956-00
MGISEQ2000-OQ/PQ	980-001622-00
DNBSEQT7-IQ/OQ/PQ	980-000961-00
DNBSEQT7-OQ/PQ	980-001634-00
MGIDLT7-IQ/OQ/PQ	980-000962-00
MGIDLT7-OQ/PQ	980-001635-00

- RUO Instrument

	IQ/OQ/IPV	OQ/IPV
Initial installation	✓	
Required after Installation		✓
After relocation	✓	

	Initial installation/After relocation	Required after Installation
Certified/regulated customer	IQ/OQ/IPV	OQ/IPV
After key parts being replaced	IQ/OQ/IPV	OQ/IPV

- Automatic equipment-RUO

Product name	Product number
MGISP100BRS-IQ/OQ/IPV	980-001656-00
MGISP100BRS-OQ/IPV	980-001660-00
MGISP100RS-IQ/OQ/IPV	980-001655-00
MGISP100RS-OQ/IPV	980-001659-00
MGISP960RS-IQ/OQ/IPV	980-001388-00
MGISP960RS-OQ/IPV	980-001535-00
MGISP-NE384RS-IQ/OQ/IPV	980-001386-00
MGISP-NE384RS-OQ/IPV	980-001663-00
MGISTP3000RS-IQ/OQ/IPV	980-001384-00
MGISTP3000RS-OQ/IPV	980-001649-00
MGISTP7000RS-IQ/OQ/IPV	980-001383-00
MGISTP7000RS-OQ/IPV	980-001652-00

- Sequencer-RUO

Product name	Product number
MGISEQ200RS (Config 1) -IQ/OQ/IPV	980-001637-00
MGISEQ200RS (Config 1) -OQ/IPV	980-001643-00
MGISEQ200RS (Config 2) -IQ/OQ/IPV	980-001638-00
MGISEQ200RS (Config 2) -OQ/IPV	980-001642-00
MGISEQ2000RS-IQ/OQ/IPV	980-001619-00
MGISEQ2000RS-OQ/IPV	980-001624-00
MGISEQ2000RSFAST-IQ/OQ/IPV	980-001618-00
MGISEQ2000RSFAST-OQ/IPV	980-001625-00
DNBSEQT7RS-IQ/OQ/IPV	980-001630-00
DNBSEQT7RS-OQ/IPV	980-001632-00

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