

## **IQ OQ PQ Documentation for the Medical and Pharmaceutical Industries**



### **Description**

IQ/OQ/PQ are three parts of a protocol used to verify and validate instrument performance in relation to regulatory requirements:

- Installation Qualification (instrument has been delivered and installed in accordance with manufacturer's requirements)
- Operational Qualification (instrument is functioning in accordance with its specification)
- Performance Qualification (instrument is continuing to meet its specification)

This documentation is specific to the serial number of the machine supplied, and is completed jointly by Mecmesin Ltd, and either the distributor or the purchaser's nominated representative who will assist with the completion of IQ and OQ as part of the normal installation and training process.

The PQ template enables the end user to maintain a structured and documented procedure, test plan and report format.

The IQ/OQ/PQ documentation is supplied as a printed copy in a ring binder, and on a memory stick for ease of completion.

Please order the IQ OQ PQ documentation pack with your machine.

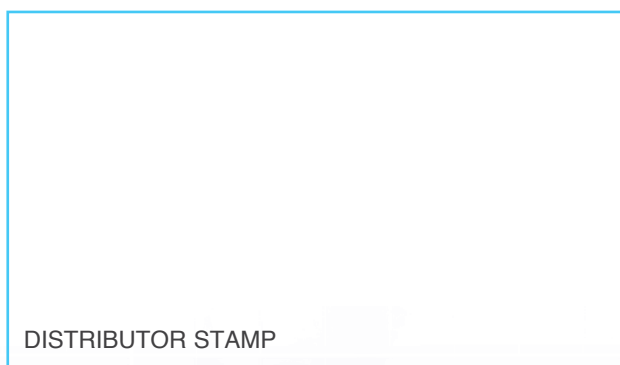
## Contents

<p><b>IQ – Installation Qualification</b></p> <p>Part 1: Instrument Details and Identification          Part 2: Instrument Specification          Part 3: Environmental &amp; Siting Consideration          Part 4: Delivery Condition &amp; Documentation          Part 5: Installation          Part 6: Summary Report</p>	<p><b>OQ – Operational Qualification</b></p> <p>Part 1 – Operational Qualification for -i system          Part 2 – Operational Qualification for -xt system          Part 3 – Summary Report</p>
<p><b>PQ – Performance Qualification</b></p> <p>Standard advice on PQ Procedure, PQ Qualification Test Plan and PQ Report</p>	<p><b>Appendices</b></p> <p>Product EC Declaration of Conformity          ISO 9001:2008 Certificate          Instrument Statement of Conformance          Safe Use Guide          Assembly and Installation Guide          Operating Manuals (where appropriate)          Organisation Chart of Mecmesin Ltd          Distributor Authorised Representative Certificate</p>



FS 58553

Mecmesin reserves the right to alter equipment specifications without prior notice.  
E&OE



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