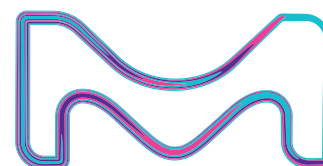


Quality Segments and Discriminating Quality Attributes

M-Clarity™ Program

Chemicals and Consumables

Discriminating Attribute	Description	MQ 100	MQ 200	MQ 300	MQ 400	MQ 500	MQ 600
Quality Standard ISO 9001	ISO 9001	•	•	•	•	•	•
	IPEC or ISO 13485					•	•
	ICH Q7 or 21 CFR medical device						•
Specifications available		•	•	•	•	•	•
Certificate of Quality or Certificate of Analysis available		•	•	•	•	•	•
Release testing is performed using established protocol		•	•	•	•	•	•
Written SOP for process control		•	•	•	•	•	•
Supplier approval process in line with corporate quality programs		•	•	•	•	•	•
Change notification available as an opt-in for individual products. Notifiable events differ between Quality Segments			•	•	•	•	•
Release testing is performed using established or published protocol			•	•	•	•	•
Site quality self-assessment available			•	•	•	•	•
Shelf life/expiration date is identified if applicable				•	•	•	•
Audits can be requested by customer				•	•	•	•
Product can be added to a Quality Agreement				•	•	•	•
Analytical method is verified					•	•	•
Analytical method may be shared upon request					•	•	•
Quality declarations as required by regulation or product application					•	•	•
Process control is verified					•	•	•
Supplier approval by paper audit or questionnaire					•	•	•
Original manufacturer disclosure may be requested with signed confidentiality commitment					•	•	•
Controls for subcontracting are established					•	•	•
Primary packaging component control					•	•	•
Original manufacturer disclosure available with signed confidentiality commitment						•	•
Analytical method is validated						•	•
Process control is validated						•	•
Supplier approval by on-site audit for critical suppliers						•	•
Shelf life/expiration date is defined by stability study						•	•
Original manufacturer disclosure available without confidentiality commitment							•
Risk based approach to controlled conditions for warehouse & shipping							•



Equipment and Spare Parts

Discriminating Attribute	EQ1	EQ2	EQ3	EQ4
Quality Standard ISO 9001	●	●	●	●
Supplier/subcontractor approval process in line with on-site audit corporate quality program	●	●	●	●
Product specifications/data package available	●	●	●	●
Certificate of Conformity or Quality or Certificate of Analysis available (where applicable)	●	●	●	●
Release testing - performed using established protocol	●	●	●	●
Site quality self-assessment available	●	●	●	●
Audits at our Life Science site can be requested		●	●	●
Equipment maintenance provided as service		●	●	●
Release test data available during an audit		●	●	●
User guide		●	●	●
On site equipment qualification (IQ/OQ) is provided as a service			●	●
Change Notification available as an opt-in for individual products			●	●
Release test data available upon request				●
Factory acceptance test offered as a service				●

Discriminating Attribute	SP1	SP2
Quality Standard ISO 9001	●	●
Supplier/subcontractor approval process in line with on-site audit corporate quality program	●	●
Site quality self-assessment available	●	●
Product specifications/data package available		●
Certificate of Conformity or Quality or Certificate of Analysis available		●
Change Notification available as an opt-in for individual products		●

To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645

Spain: 901 516 645 Option 1

Germany: 069 86798021

Switzerland: 0848 645 645

Italy: 848 845 645

United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: [MerckMillipore.com/offices](https://www.MerckMillipore.com/offices)

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