



M-Clarity™ Program

Matrix of Notifiable Changes

Chemicals and Consumables

Notifiable Change	Change Notification Commitments Supported per Quality Segment					
	MQ 100*	MQ 200	MQ 300	MQ 400	MQ 500	MQ 600
Discontinuation of ISO certifications (e. g. ISO 9001, ISO 14001, ISO 13485, FSSC 22000 where applicable)	✓	✓	✓	✓	✓	✓
Change to published/analytical release specification acceptance criteria (excluding compendial specifications)	✓	✓	✓	✓	✓	✓
Obsolescence - catalog number is discontinued	✓	✓	✓	✓	✓	✓
Releasing QC testing Site	✓	✓	✓	✓	✓	✓
Downgrade of Quality Segment or change of Quality Segment category	✓	✓	✓	✓	✓	✓
Revision of Discriminating Quality Attribute/Matrix of Notifiable Changes	✓	✓	✓	✓	✓	✓
Shelf Life (expiration date or recommended retest date)	✓	✓	✓	✓	✓	✓
Change of our immediate supplier - no disclosure of source	✓					
Change to primary manufacturing and/or repackaging/downfilling site	✓	✓	✓	✓	✓	✓
Change in test method (non-compendial) and those affecting quality document (CoA/CoQ or label)	✓	✓	✓	✓	✓	✓
Changes in the manufacturing process impacting specification, where process uses a substantially different route of synthesis or manufacture (chemicals)	✓	✓	✓	✓	✓	✓
Primary packaging materials and/or container closure/ Change in materials of construction (not including customized packaging)	✓	✓	✓	✓	✓	✓
Change to raw materials affecting the CoA or CoQ or specification	✓	✓	✓	✓	✓	✓
Labeling - Change to item name or number / Changes in the labeling regarding product name, specification, shelf-life or storage	✓	✓	✓	✓	✓	✓
Change in the nature of the raw materials with TSE/BSE relevance resulting in an increased risk for the finished product with respect to EMA/410	✓	✓	✓	✓	✓	✓
Changes in the manufacturing process impacting specification, or intended use, form/fit/function (disposable/devices/single use items only)	✓	✓	✓	✓	✓	✓
Change of Original Manufacturer (OM) - disclosure of OM not guaranteed (Confidentiality Commitment required in case of disclosure)	✓					
Changes to the equipment - impacting the manufacturing process, specifications or intended use	✓	✓	✓	✓	✓	✓
Change in GMP Status					✓	✓
Change of Original Manufacturer (OM) - disclosure with Confidentiality Commitment					✓	
Change of general transport conditions				✓	✓	
Changes to instructions for use and change in risk level						✓
Change of Original Manufacturer (OM) - disclosure w/o Confidentiality Commitment						✓
Change of CEP revision						✓

*Notifiable changes are not applicable for the quality segment MQ100

Equipment and Spare Parts

Notifiable Change	EQ1*	EQ2*	EQ3	EQ4	SP1*	SP2
Obsolescence of product			✓	✓		✓
Downgrade of Quality Segment or change of Quality Segment category			✓	✓		✓
Revision of Discriminating Quality Attribute/ Matrix of Notifiable Changes			✓	✓		✓
Changes requiring retrofit			✓	✓		
Major software changes				✓		
Changes affecting form, fit or function						✓
Changes to raw materials in contact with the fluid path						✓

*Notifiable changes are not applicable for the quality segments EQ1, EQ2 and SP1

