

Title: Waters GSS – Service Alert “Qualification Documentation Binder Update”

Document No: 715005925

Version No: 02

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*Description:

The Compliance Documents binder, supplied with our qualification services and used to store qualification documentation, has been updated. These binders are shipped as part numbers 290001138 and 290001139.

*Information:

The update of the binder includes the following:

- A new revision of the Qualification Overview, part number 715511111 has been created. This overview is meant to be inclusive of all Waters qualification products. It contains a revision history indicating the changes from the previous revisions.
- A new revision of Recommended Qualification Procedures Following Repair, part number 715005511, has been created. This revision of the document is meant to be inclusive of all Waters qualification products. It contains a revision history indicating the changes from the previous revisions.
- The binder tab that was labelled Performance Qualification has now been changed to Supporting Documentation. Performance Qualification (PQ), by definition from USP1058, is the documented collection of activities necessary to demonstrate that an instrument consistently performs according to the specifications defined by the user, and is appropriate for the intended use. This is a customer performed activity. Waters will be working to update our qualification products and documents to remove the reference to Performance Qualification as they come up for revision.

Due to inventory logistics, there will be a period where customers may receive binders with the previous revision of the documents listed above. The customer may choose to use that revision, or the Waters representative can provide the customer with the new revision which is available electronically through Service Assist.

Also, the Qualification Overview provided electronically on the Empower SystemsQT Products DVDs may be the previous revision until those DVDs are updated to their next revision. The customer may choose to use the revision on the DVD, or the revision that is supplied in the Compliance Documents binder. The Waters representative can provide the customer with the new revision which is available electronically through Service Assist.

*Environment:

Part numbers affected:

290001138 – Binder, 3 Ring, Compliance Package

290001139 – Binder, 2 Ring, Compliance Package

*Service Action Required:

For qualification documentation that is labelled Performance Qualification (PQ) or Operational Qualification/Performance Qualification (OQ/PQ), place it in the Operational Qualification (OQ) section of the binder.

The Supporting Documentation section of the binder may be used for documentation that is pertinent to the qualification, but does not have a discrete binder section. Discuss the placement of these types of documents with the customer prior to performing the qualification service.

A copy of this Service Alert may be placed with the qualification documentation.

***Critical Service Alert:** ☐ Yes ☒ NO If YES, choose one of the following that applies:

- ☐ Impacts data integrity
- ☐ Impacts health and safety of a Waters employee or customer
- ☐ Retrofit (priority 3 or 4)

*Mandatory fields

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DOCUMENT HISTORY

VERSION:	00	ORIGINATOR:	Ginny Halfpenny	Change ID:	N/A	Create Date:	27JUL2018
SUMMARY OF CHANGE: NEW DOCUMENT CREATED							
VERSION:	01	ORIGINATOR:	Ginny Halfpenny	Change ID:	N/A	Create Date:	21FEB2019
SUMMARY OF CHANGE: DOCUMENT UPDATED TO THE LATEST TEMPLATE. TYPOGRAPHICAL ERROR FIXED IN THE SERVICE ACTION REQUIRED SECTION (DISCREET CHANGED TO DISCRETE).							
VERSION	02	ORIGINATOR	Ginny Halfpenny	Change ID:	N/A	Create Date:	02NOV2020
SUMMARY OF CHANGE: DOCUMENT UPDATED TO INCLUDE DETAILS THAT THE RECOMMENDED QUALIFICATION PROCEDURES FOLLOWING REPAIR DOCUMENT MAY ALSO BE A DIFFERENT REVISION DUE TO INVENTORY LOGISTICS.							