


**Notification date:** February 7, 2020

**Notification reference number:** CN-RPII-BLHN8H (Revision 1- Implementation date change)

## Product Change Notification

<b>Purpose</b>	This is a Pall driven change to the quality release test procedure of certain Emflon® PFR products.
<b>Affected products</b>	Multiple filter products are impacted by this change: Refer to Appendix 1 for the parts listing.
<b>Change to fluid or air contact component (s)?</b>	No
<b>Change process stages</b>	Formal notification: Issued on Feb 7, 2020 Revision 1 issued: March 16, 2020 (this document) Revised date for change implementation: <b>March 23, 2020</b>
<b>Pall manufacturing plants impacted</b>	Pall Fajardo, Puerto Rico Pall Ilfracombe, UK
<b>Customer action required</b>	None
<b>Pall point of contact</b>	Please email your inquiries about this change to: <a href="mailto:customernotification@pall.com">customernotification@pall.com</a>
<b>Authorized by</b>	  Mark Baree Quality Director Biotech Consumables

### Description of change

Pall Life Sciences will change the test fluid used for integrity testing of certain Emflon PFR products at quality release testing from 25/75 (v/v) Tertiary butyl alcohol (TBA)/Water to 60/40 (v/v) IPA/Water. This action is being taken to standardize the test method used for all Emflon PFR products and to maximize efficiency at test.

In anticipation of an increased demand of the products in scope we will accelerate the date of implementation from May 11<sup>th</sup> to March 23<sup>rd</sup>. This will enable us to immediately leverage a capacity increase and maintain security of supply.

### Reason for the change

To standardize the quality control (QC) release testing methodology across the entire Emflon PFR product range.

### Impact on customer operations and/or recommended action(s)

This notification is for information purposes only.

All materials of construction of the affected products are currently used in the manufacture of other Emflon PFR products already subjected to the use of 60/40 (v/v) IPA/water as the test fluid for QC release.

Pall expects minimal risk to end-users and no changes to product fit, form or function.

### Additional information

This information is being provided to you to serve as notification so that you can assess impact on your receipt and incoming inspection operations. If anyone else within your organization should be made aware of this notification, please forward them a copy of this letter or advise us accordingly.

Please email your inquiries about this change to: [customernotification@pall.com](mailto:customernotification@pall.com)

This notification has been cleared for release by Pall Quality Assurance.

We appreciate your continued use of Pall products.

**Appendix 1 – Affected part numbers list**

<b>Part Number</b>	<b>Part Number</b>	<b>Part Number</b>	<b>Part Number</b>
6040561	KA3PFRP6	MCY4440PFRPH4	MCY4463PFRPVH4
C2PFRP1	KA3PFRW1	MCY4440PFRPH4MR	MCY4463PFRWH4
C2PFRP1A	MCY2220PFRWH4	MCY4440PFRPH4SBL	SBF1PFRPH1
C2PFRP1B	MCY2230PFRPH	MCY4440PFRPJ	SBF1PFRPH4
C2PFRP1C	MCY2230PFRPH4	MCY4440PFRWH4	SBF1PFRPJ
C3PFRP1	MCY2230PFRPJ	MCY4440PFRWJ	SBF1PFRWH4
C3PFRP150	MCY2230PFRWH4	MCY4463PFRPH	SKA3PFRP1
C3PFRP1A	MCY3330PFRPH	MCY4463PFRPH1	SLK7001PFRP
C3PFRP1ASBL	MCY3330PFRPH4	MCY4463PFRPH4	SLK7001PFRPNPL
C3PFRP1B	MCY3330PFRWH4	MCY4463PFRPH4NPL	SLK7002PFRP
C3PFRP1BGN	MCY4440PFRPH	MCY4463PFRPJ	SLK7002PFRP25
KA3PFRP1	MCY4440PFRPH1	MCY4463PFRPJ24	SLK7002PFRPNPL

**Document History**

<b>Document name</b>	<b>Description</b>	<b>Date Issued</b>
CN-RPII-BLHN8H	Original notification	Feb. 7, 2020
CN-RPII-BLHN8H (Revision 1)	Changes the implementation date from May 11, 2020 to March 23, 2020	March 16, 2020