

## **CUSTOMER CHANGE NOTIFICATION**

Reference: CC-34

01/05/2024

Dear Valued Customer,

This letter serves as formal notification of changes that affect products purchased by your organization.

## **Change Description**

| Part Number(s) Affected: | 118-162-101<br>118-162-101CS   |
|--------------------------|--|
|                          | 118-162-131  |
|                          | 118-162-131CS  |
| Description of Change:   | Additional product specifications added:<br>TOC (before packaging) <500ppb<br>Conductivity (before packaging) <1.3µS/cm @ 25°C   |
| Reason for Change:       | Additional QC testing added to qualify product as Water, Cell<br>Culture, WFI Quality as found in the USP (United States<br>Pharmacopeia) for Water for Injection (WFI) before<br>packaging. |
|                          | This product is intended for research use and further manufacturing only. This product is not intended for diagnostic or therapeutic use.  |

## **Implementation and Next Steps**

Product orders and shipments from January 22,2024 forward will be against these revised specifications. The Certificate of Analysis for a particular lot will accurately reflect the specifications in effect at the time of testing.

We trust this documentation is acceptable for your files. Please inform us of your acceptance of this change. Should you have any questions or concerns regarding this notification, please contact me at curleyj@qualitybiological.com.

Sincerely,

Jeanmar Digitally signed by Jeanmarie Curley ie Curley <sup>Date: 2024.01.05</sup> 14:49:38 -05'00'

Vice President, Quality Assurance