

December 7, 2018

**CUSTOMER NOTIFICATION**  
**Product CHANGE: Inclusion of an Expiration Date**

Dear Valued Customer:

As part of continuous product improvement, WaterSep BioSeparations Corporation is changing our hollow fiber cartridge Product Labels and Certificates of Analysis to include an expiration date of 24 months from date of labeling. A summary is included on page 2 of this notice.

Affected Products	Catalog Codes Beginning with:
Green Line	SU-
ReUse Line	WA- or BA-
Steamer Line	AU-

Our records indicate that you purchased an affected product(s). WaterSep endeavors to deliver the highest quality products and make product improvements with as little disruption to your process as possible. Therefore, a copy of this notification should be forwarded immediately to the end users, departments and QA groups that may be affected by this change.

WaterSep BioSeparations appreciates your use of our hollow fiber products and looks forward to continuing to service your filtration needs.

Please do not hesitate to call me at 508 970 0089 x 207, M-F 9-3pm EST so that I may address any specific concerns you may have regarding this notification.

*Julie-Anne Burdick*

Julie-Anne Burdick, PhD., CSQP

Quality Assurance Team

[WaterSep BioSeparations Corporation](http://www.WaterSep.net)



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ISO 9001:2015 Certified. Registration #19.8073

## SUMMARY OF WATERSEP PRODUCT CHANGE

<p>Change Description with an example</p>	<p>Include an expiration date on all cartridge product labels (see example label below) and Certificates of Analysis (CofA).</p> <p style="text-align: center;"><b>WaterSep</b>                      <b>Investigator24 Green</b></p> <p>Membrane: m-PES, 30K Dalton                      Lumen ID: 1.0 mm</p> <p>Surface Area: 0.28 M2                      <span style="border: 1px solid red; padding: 2px;">Exp. Date: 12/6/2020</span> </p> <p>Dimensions: 1.3" x 24"                      </p> <p>Max Temp: 60°C                      Max Pressure: 40psi @ 20°C</p> <p>Cat #: SU 030 10INV24 S0                      Lot #: 181206001D</p>
<p>Reason for change</p>	<p>Continuous improvement to include product expiration dates on the labels and CofA.</p>
<p>Expected impact and/or consequences of change</p>	<p>Minor change. Improvement to product labels and CofA information. Change does not affect product design or materials of construction.</p>
<p>Date of change</p>	<p>The improvement to all the WaterSep products will be implemented starting December 7, 2018. You may start receiving your order with these changes starting December 7, 2018.</p>
<p>Identification of product made with new material</p>	<p>The 24-month expiration date is included on the product label as “Exp. Date: MM/DD/YYYY” and on the Certificate of Analysis. WaterSep has the ability to trace these changes based on lot number.</p>
<p>Changes to release testing procedures, specifications or validation</p>	<p>None.</p>
<p>Changes in animal origin status</p>	<p>None.</p>
<p>Changes to shelf life</p>	<p>An improvement to the product labeling includes the expiration date and CofA includes the shelf life date and duration of 24 months from date of labeling. WaterSep defines the expiration date and the shelf life date as the date up until an unopened product can be used, provided the product has been stored at room temperature in unopened, original packaging.</p>
<p>Changes to Certificate of Quality Assurance or labeling</p>	<p>Shelf life date and duration of 24 months from date of labeling will be included on the product CofA and expiration date will be included on the product label. <u>Note:</u> Custom assemblies made with the WaterSep cartridges may have a reduced expiration date based on the expiration date of all the components in the assembly. The expiration date of custom assemblies is given on the assembly product label and the shelf life date of the assembly is reported on the Quality Assurance Certificate.</p>
<p>Changes in packaging, shipping, or storage</p>	<p>None. WaterSep defines the product expiration date as the date up until an unopened product can be used, provided the product has been stored at room temperature in unopened, original packaging.</p>