

# Advisory Notice

**Date Released:** 2026-March-19  
**Posted By:** Quality Assurance  
**Product Affected:** All Finished Monobind Kits  
**Brief Description of Advisory:** IFU and SDS updates to meet regulatory standards and for greater clarity

As part of Monobind's update to its **Primary Packaging** for AccuBind® ELISA and AccuLite® CLIA products, the IFU has been modified. This was made for improved descriptions (specifically; product name, configurations, types of external quality controls used) and to meet updated regulatory standards (icons, ISO and the EU REP). No modifications were made to test procedures, product contents or performance statements. **Instructions for Use modifications as follows:**

<b>Section Initial: Image and Product Name</b>	
<b>Current</b>	<b>New</b>
Logo image is <sup>TM</sup> <b>marked</b> AccuBind <sup>TM</sup> or AccuLite <sup>TM</sup>	Logo image is ® <b>marked</b> AccuBind® or AccuLite®
Analyte name	Includes AccuBind® ELISA Test System or AccuLite® CLIA Test System ( <i>better match of FSC and Invoice</i> )
<b>Section 11: Quality Control</b>	
<b>Current</b>	<b>New</b>
Four out of six quality control pools should be within the established ranges.	If used, 2 of 3 quality control pools should be within the established range. <i>(better match to most commercial control products)</i>  <i>Or if controls are included the statement is:</i> (Optional) 2 of 3 commercial quality control pools should be within the established ranges.
No mention of internal controls ( <i>when included</i> )	All provided kit controls should produce results within the established ranges.
<b>Section 12: Risk Analysis</b>	
<b>Current</b>	<b>New</b>
The MSDS and Risk Analysis Form for this product are available on request from Monobind Inc.	The SDS is available at <a href="https://www.monobind.com/safety-data-sheets">https://www.monobind.com/safety-data-sheets</a> and the Risk Analysis Form may be requested.
<b>Section 16: Available Configurations</b>	
<b>Current</b>	<b>New</b>
There is no section 16, only a table of available sizes was present with no information on available products and item numbers	Added Section 16 details products: item numbers, descriptions and contents more clearly related to the table of components, including links to website
Does not mention external Monobind controls	Added any related QSure® control information
<b>Section End: Regulatory Image</b>	
<b>Current</b>	<b>New</b>
EN 980/ ISO 15223	ISO 15223 ( <i>EN 980 phased out/ no longer used</i> )
EC REP term used with name provided	EU REP (new term as 'EC REP' is replaced, and name of REP no longer in the IFU - on outside kit label only as permitted by IVDD and IVDR standards)

**SDS Modifications:**  
Revision number/ effective date and updates to comply with requirements of Commission Regulation (EU) 2020/878.

**Trails**  
As a reminder, Distributors may access Technical Files, including IFU and other sections, from the [Trails website](#) in Documents > Kit or Controls, Instruments or Company Certifications. For access, please contact [customerservice@monobind.com](mailto:customerservice@monobind.com). The Trails and Monobind's website have been updated with the revised labeling, including Sample Labels and IFU, as well as the SDS – as available - currently ELISA completed.

As an official of the company, I verify this information to be true and correct.  
 Anthony Shatola | Quality Control Director  
 On behalf of: [regulatory@monobind.com](mailto:regulatory@monobind.com) 

