



LETTER OF EXPLANATION

To Whom It May Concern:

We, Beckman Coulter, Inc., 250 South Kraemer Blvd., Brea, California 92821 USA, hereby confirm that the below mentioned products are undergoing a minor design change for the IFU and labeling. The minor changes being made comply with the EU Regulation 2017/746. The primary changes are the change in address of the EC Representative from Switzerland to Ireland for products that have Beckman Coulter, Inc, Brea, CA USA identified as the manufacturer and the addition of a patent statement. There are no changes to product design or function.

Product Number	Product Name
81901	Access Reaction Vessels
386167	UniCel DxI Reaction Vessels
81902	2.0 mL sample cups
81915	1.0 mL/13 mm insert cups
81920	1.0 mL/13 mm insert cup caps
81917	2.0 mL/16 mm insert cups
81914	3.0 mL sample containers
81922A	3.0 mL sample container caps
81916	Pediatric insert cups, 1.0 mL
651412	Sample cup, 0.5 mL
652730	Sample cup, 2 mL
81911	Contrad 70 (Contrad)
81912	Citranox

IFU Updates: N/A; there are no IFUs for these consumable products.

General Labeling Changes:

Section	Change
Manufacturer's Address	Add phone number
Information for USA Only box	Add: May be covered by one of more pat. – see www.beckmancoulter.com/patents
Technical documents website address	Changed to beckmancoulter.com/techdocs
EC Rep	Change in the address for the authorized representative to: Beckman Coulter Ireland Inc. Lismeehan O'Callaghan's Mills Co. Clare. Ireland Tel: +(353)(0)65 683 1100



General Labeling Changes:

Product Type	Label Type	Changes
RVs and Sample Cups	LABC	<ul style="list-style-type: none"> Addition of BEC telephone number to the legal manufacture address Addition of Instructions for Use symbol and BEC website address for IFUs
	LABK (P2)	<ul style="list-style-type: none"> Remove HIBC barcodes from variable print section Addition of patent statement Correct BEC website address for IFUs
	LABK (Kit Box)	<ul style="list-style-type: none"> Addition of BEC telephone number to the legal manufacture address Update the EC Rep address from Nyon to County Clare, if applicable Update website address on SDS symbol

Product Specific Changes:

Product Name	Item	Label Type	From:	Change To:
Contrad 70 (Contrad)	81911	LABC	<ul style="list-style-type: none"> Single label applied to back of kit box 	<ul style="list-style-type: none"> Replace single label with a booklet attached to kit box Addition of hazard and precaution statements Addition of the formula for chemical(s) related to hazard information The booklet will provide all hazard information translated into all required EU languages
Citranox	81912	LABC	<ul style="list-style-type: none"> Single label applied to back of kit box 	<ul style="list-style-type: none"> Replace single label with a booklet attached to kit box Addition of hazard and precaution statements Addition of the formula for chemical(s) related to hazard information The booklet will provide all hazard information translated into all required EU languages

We confirm that the above change(s) will not alter product performance, intended purpose, raw material composition, stability studies, manufacturing site and processes.

DocuSigned by:

Long, Harry J

Signer Name: Long, Harry J
 Signing Reason: I approve this document
 Signing Time: 16-May-2022 | 8:48:54 AM PDT

7F5399DE85BD4BE5B3967F6814CF701D

Harry Long
 Manager Regulatory Affairs