

TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 137

To:

It is our intention to change the Manufacturing Process of the products listed below. The details of the change and the reason for it are given below.

Please acknowledge receipt of this notification and confirm your acceptance of the change by completing the section below and emailing a copy of the form to qc@tcsgroup.co.uk. Acceptance of the change is assumed if a response is not received within two weeks of issue of this notification.

If you have any difficulties or concerns accepting the change, please contact us immediately.

Product: See attached.

Proposed Change Date:: 14-04-2025

Change Details:

Change to bag design on the above product codes, these products are supplied in 2,4,7 and 10L bags. The change is required due to the incumbent supplier restricting availability on these bag lines. We have taken the opportunity to develop the bag design to incorporate some customer design requests.

Reason for Change:

The incumbent supplier has restricted supply on one bag line and has indicated further restrictions will apply to the remainder of the product range, forcing TCS to find a long term supply option.

Considerations:

Extensive trials were held in house to ensure the bag quality, supply chain and end product quality were not affected by the proposed change. There is no significant difference in the connections available to the user, these have been kept consistent with the current supply.

Conclusion

The bags and their design have passed the TCS product trial criteria and incorporates customer design change requests.

The change ensures long term stability of supply to both TCS and our customers.

I understand and accept the changes proposed to the product given above.

Signed:

Date:

Position:

On Behalf of (Company):

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Registered in England No. 2172900 Vat No. GB 729 8545 85

TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 137 (continued)

APPENDIX 1

DEFIBRINATED HORSE BLOOD		
Product codes	Volume	
HB001B	1LTR	
HB001L	BULK	
HB003B	1.1 LTR	
HB079B	1.5LTR	
HB002B	2LTR	
HBO68B	2.7LTR	
HB058B	3LTR	
HB099B	3.5LTR	
HB014B	4 LTR	
HB004B	5LTR	
HB011B	5.5LTR	
HB009B	6LTR	
HB007B	7 LTR	
HB005B	7.8LTR	
HB008B	8LTR	
HB071B	10LTR	

DEFIBRINATED SHEEP BLOOD		
SB006L	BULK	
SB006L	BULK	
SB001B	1LTR	
SB009B	1.5LTR	
SB003B	2LTR	
SB113B	3LTR	
SB1012B	3.1LTR	
SB014L	BULK QA	
SB116B	9LTR	
SB095B	10LTR	
SB005B	5LTR	
SB002B	7LTR	
SB210B	10LTR PCV	
SB094B	800ML	

LYSED HORSE BLOOD		
HB069B	2.6LTR	
HB070B	5LTR	

WASHED SHEEP ERYTHROCYTES		
SB114B	2LTR	
SB115	2.6LTR	