

TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 137 v2

To: Customers purchasing horse and sheep blood products

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:: Phase in from 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.

V2 – Proposed change date updated to state 'phase in' as some stocks of bags from the incumbent supplier are still available for production use. New bags will be phased in from 14-04-2025 as stocks of existing bags become depleted.

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

Signed:

Date:

Position:

On Behalf of (Company):

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TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 137 v2 (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

LYSED HORSE BLOOD	
HB069B	2.6LTR
HB070B	5LTR

DEFIBRINATED SHEEP BLOOD	
Product codes	Volume
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

WASHED SHEEP ERYTHROCYTES	
SB114B	2LTR
SB115	2.6LTR