



TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 95

To: Customers and Distributors of animal blood and serum products

It is our intention to change the status 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 one month of issue of this notification.

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

Product: Animal Blood and Serum products - see Appendix 1 for full list of products and product codes

Proposed Change Date: 26 May 2022

Change Details:

These products will no longer be classed as *in vitro* diagnostic products (IVDs). The labels for these products will not include the CE or IVD symbols.

Reason for Change:

Currently the products listed in Appendix 1 are classified as IVDs in accordance with Annex III of Directive 98/79/EC and a self-declaration of conformity is available for each product.

Directive 98/79/EC is to be replaced by Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) for which the date of application is 26 May 2022.

It is a requirement of the IVDR to reclassify all IVDs in accordance with the classification rules. None of the seven classification rules applies to the animal blood and serum products listed in Appendix 1.

As the animal blood and serum products are used as raw materials in manufacture and not as finished products for *in vitro* diagnosis of patients it will also not be possible to meet all the IVDR requirements for conformity assessment and performance evaluation.

For these reasons the products in Appendix 1 will no longer be classed as IVDs.

Considerations

The removal of the CE and IVD symbols will have no impact on the manufacturing processes or quality of the products listed in Appendix 1; the change described is solely the removal of IVD status.

These products will continue to be suitable as raw materials for manufacture of IVDs.

TCS Biosciences will retain and maintain the ISO 9001:2015 quality management system, ISO 14001:2015 environmental management system and ISIA (International Serum Industry Association) Traceability Certification in accordance with current practices.

There is no impact on the issue of certificates of analysis for the products listed in Appendix 1.

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 95 (continued)

APPENDIX 1:

Product	Product codes
Horse Blood Defibrinated	HB001, HB001B, HB001L, HB002, HB0032B, HB003B, HB004B, HB005B, HB008B, HB009B, HB011B, HB012, HB014B, HB028B, HB029, HB030, HB031, HB032, HB033, HB034, HB035, HB035B, HB035T, HB051B, HB057B, HB058B, HB061, HB062B, HB064B, HB065, HB068B, HB071B, HB074B, HB077B, HB079B, HB095B, HB099B
Horse Blood Defibrinated QA	HB013L
Horse Blood in ACD	HB015, HB045, HB046, HB047
Horse Blood in Alsever's	HB048, HB049, HB050
Horse Blood in EDTA	HB073, HB076, HB082
Horse Blood in Heparin	HB054
Horse Blood Formolised	HB042, HB043
Horse Blood Lysed	HB024, HB025, HB026, HB036, HB037, HB038, HB038B, HB052B, HB056, HB056B, HB059, HB063B, HB069B, HB070B, HB072B, HB080B, HB093B
Horse Blood Oxalated	HB039, HB040, HB041, HB108
Donor Horse Serum, Defibrinated UK Origin	HA001, HA001S, HA002, HA002G, HA201, HA201S, HA202, HA202S
Donor Horse Serum, Heat Inactivated UK Origin	HA005, HA006
Sheep Blood Defibrinated	SB001, SB001B, SB001T, SB003, SB003B, SB006L, SB008B, SB009B, SB012B, SB013B, SB053, SB054, SB055, SB055B, SB055T, SB090, SB092, SB094, SB094B, SB94T, SB113B, SB115
Sheep Blood Defibrinated QA	SB014L
Sheep Blood Defibrinated and Saline	SB072
Sheep Blood in ACD	SB007, SB065, SB066, SB067, SB079
Sheep Blood in Alsever's	SB068, SB069, SB070, SB091
Sheep Blood in EDTA	SB111
Sheep Blood Formolised	SB062, SB063, SB064
Sheep Blood in Heparin	SB075, SB078
Sheep Blood Lysed	SB056, SB058
Sheep Blood Oxalated	SB060
Washed Sheep Erythrocytes	SB114B, SB115