



Blood and Transplant

14 Estuary Banks
Estuary Commerce Park
Speke
Liverpool
L24 8RB

23rd August 2019

Tel: 0151 268 7000
Fax: 0151 268 7001
www.nhsbt.nhs.uk

Dear Customer

Re: Update to Notified Body and European Representative for NHSBT Reagents

Due to the imminent UK exit from the EU, NHSBT Reagents can confirm the successful transition of notified body from Underwriters Laboratories (UL) to the Polish Centre for testing and certification (PCBC) and the appointment of Quality First International (QFI) as the EC Authorised representative.

These changes require the update to our product labels, instructions for use and other regulatory documentation for all products that can potentially be shipped to Europe and the Rest of the World Markets.

The PCBC certificates are now available and can be found on our website at blood.co.uk/Reagents. There is a 6-month transition period from the date of the certificates in which the UL notified body number of 0843 can continued to be used.

CE marked products classified under Annex II manufactured from 4th November 2019 will bear the CE mark of PCBC and will therefore be labelled with the notified body number of 1434. Products manufactured and released for sale prior to this date can continue to reference the notified body number 0843 and these remain acceptable until expiry.

From the same date the all associated instructions for use and other regulatory documents will also be updated with the new notified body number.

Subject to ratification of the date of the UK exit from the EU, at the same time the name of the EC Authorised representative will also be present on NHSBT Reagents' instructions for use.

NHSBT Reagents consider this to be formal notification of the proposed changes and will continue to update you with any further developments if necessary.

If you require any further advice or information in relation to this notice, please contact Reagents Customer Services who will direct you to the correct individual for your enquiry.

We thank you for your continued custom.

PP 

Michelle Weston

Reagents Manager

Reagents customer services 0151 268 7157