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## **Notification letter**

## Bordier ELISA kits' instructions for use revision

Concerned products references: 6100, 9200, 9250, 9300, 9310, 9350, 9400, 9450, 9500, 9550, 9600, 9650, 9700, 9750 and 9800.

Dear Sir/Madam,

In the next months, our products will be packed with updated instructions for use (IFUs) following the obtaining of the European regulation 2017/746 certificate of conformity.

Significant changes are the following:

- <u>Intended use of the product</u>: replacement of "quantitative detection" by "qualitative detection".
- <u>Warning and precautions</u>: addition of the "corrosive" hazard pictogram for stopping solution.
- <u>Interpretation</u>: addition of a recommendation for interpreting optical density measurements overflowing the microplate reader measurement range.
- <u>Precision</u>: correction of the variation coefficients for reproducibility following the observation of a calculation error.

Please find attached an example of IFU highlighting the changes in red.

## <u>Please note that the kits composition has not been modified and the protocols and performances of the products remain unchanged.</u>

The new IFUs are valid upon receipt of this notification. They are available for download on our website or on request by phone or email.

Do not hesitate to contact us for any questions or comments.

At Crissier, September 10<sup>th</sup>, 2025

Nicolas Beyls Quality assurance manager