

SUBJECT: Modification of the specification of material FBS Ultra-low endotoxin

1- INFORMATION ON PRODUCT CONCERNED BY THE NOTIFICATION:

Catalogue Number: S1860

Batch Number: Not applicable

Production date: All batches sold after 01/06/2023

2- DESCRIPTION OF THE NOTIFICATION:

Description: Biowest currently produces batches of Fetal Bovine Sera with Ultra Low Endotoxin level, sold under material code S1860. The acceptance criteria to consider a batch as Ultra Low Endotoxin is < 0.1 EU/ml.

In order to know if this specification was adapted to customer needs, Biowest compared this specifications to competitors specifications and analysed several scientific studies on impact of endotoxin level on cells. The minimal endotoxin level that be found to have a negative impact on some specific cell lines is 1 EU/ml. This is consistent to most stringent competitors specification (< 1 EU/ml).

So, Biowest decided to increase its upper limit for FBS Ultra Low Endotoxin. In order to keep a safety margin the new specification is ≤ 0.5 EU/ml.

Documents linked: FT.S1860an version date : 31/05/2023

3- PREVENTIVE / CORRECTIVE ACTION TO REALISE:

Description: Not applicable

Written by: Jean-Philippe
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Position: Quality Manager

Date: 31/05/2023

Signature:

