

## Notification Sheet

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Nº: 80

Version 03

Date of the version: 28/05/2015

SUBJECT: Adjustment of the pH specifications of L0615: Dulbecco's Phosphate Buffered Saline w/o Calcium w/o Magnesium

## 1-INFORMATION ON PRODUCT CONCERNED BY THE NOTIFICATION:

Catalogue Number: L0615 Batch Number: Not applicable

Production date: Batches produced from 01/08/2022

Request Number: Not applicable

## 2- DESCRIPTION OF THE NOTIFICATION:

Description: After analyzing more than 200 batches of L0615 produced, Biowest came to the conclusion that its pH specifications (7.0-7.6) were a little too low.

The average pH of those batches is around 7.5. So the new specifications will be 7.2-7.8.

Documents linked: Technical Data Sheet and Safety Data Sheet of L0615

## 3- PREVENTIVE / CORRECTIVE ACTION TO REALISE:

Description: Not applicable

This change has no impact on product quality as no change is made on its composition.

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Position: Quality Officer

Date: 28/07/2022

Signature:

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