

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.

Written by : M. Varlet

Position : Quality Officer

Date : 28/07/2022

Signature :



BIO WEST
SAS au capital de 884 400 Euros
Rue de la Caille - BP 1
49340 NUAILLE - France

For more information, please contact :

BioWest
Rue de la Caille
BP11
49340 NUAILLE

Tél : 02 41 46 42 42
Fax : 02 41 46 38 90

Tél : +33 (0)2 41 46 42 42
Fax : +33 (0)2 41 46 38 90
RCS Angers B 41833441
N° Siret 311 843 652
N° TVA intracommunautaire FR 2141833441