

## **Quality System Statement**

Lifecycle Biotechnologies, LP certifies that the following product is produced, processed, packaged and held in compliance with a quality system certified to ISO 13485:2016.

Lifecycle Biotechnologies, LP maintains a quality system that has been inspected and certified to ISO 9001:2015 and ISO 13485:2016. Our ISO Registration numbers are as follow:

REGISTRATION NUMBER:

CERT-0119063 (ISO 9001:2015)  
CERT-0119061 (ISO 13485:2016)

CERT-0144709 (ISO 9001:2015)  
CERT-0144708 (ISO 13485:2016)

## **Gluten Free Statement**

To the best of our knowledge, all Lifecycle Biotechnologies LP., products, which are manufactured, processed, and packaged at our facilities, are Gluten Free. We do not add any gluten containing ingredients to our products.

Lifecycle has not tested its products for Gluten.

## **Aflatoxin Free Statement**

To the best of our knowledge, all Lifecycle Biotechnologies LP., products, which are manufactured, processed, and packaged at our facilities, are free of Aflatoxin. We do not add any Aflatoxin containing ingredients to our products.

Lifecycle has not tested its products for Aflatoxin.

## **Latex Statement**

Lifecycle Biotechnologies LP. products are not manufactured with natural rubber latex. Lifecycle's packaging, handling and manufacturing processes exclude the use of, or contact with, latex materials.

The US FDA has stated that "Contact with devices containing natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins."

The European Commission has stated that "Persons who know or suspect that they may have Type I latex allergy must avoid contact with latex products. If they are treated in healthcare they should inform the personnel about their allergy."

Lifecycle has not tested its products for natural rubber latex allergenic proteins.

## **Melamine Statement**

To the best of our knowledge, all Lifecycle Biotechnologies LP., products, which are manufactured, processed, and packaged at our facilities, are free of Melamine. We do not add any Melamine containing ingredients to our products.

Lifecycle has not tested its products for Melamine.

## **Nitrosamine Statement**

Lifecycle Biotechnologies LP., has evaluated products, that are manufactured, processed, or packaged at its facility, and have determined that potential sources of nitrosamines are of negligible risk.

The following potential sources are not performed at Lifecycle biotechnologies facilities:

1. Use of sodium nitrite or other nitrosating agents in the presence of secondary, or tertiary amines, or quaternary ammonium salts within the manufacturing process at the same or different process steps.
2. Use of sodium nitrite or other nitrosating agents in combination with reagents, solvents, and catalysts, which are susceptible to degradation to secondary or tertiary amines within the same or different processing steps.
3. Use or contaminated starting materials, intermediates or primary packaging materials.

Lifecycle has not tested its products for nitrosamine.

If you would like additional information on any of these statements, please feel free to contact us.