

ANIMAL ORIGIN STATEMENT

To the extent of the limitations of warranty cited below, MicroBioLogics provides this “*Animal Origin Statement*.”

Compliance and Conformity.

MicroBioLogics’ FDA QSR Compliance and ISO 9001:2000 conformity, contributes to the monitoring of animal origin raw materials. MicroBioLogics defers to their vendor’s “*Animal Origin Position Statement*,” as provided to MicroBioLogics for reference concerning BSE (bovine spongiform encephalopathy).

MicroBioLogics’ Vendor’s Certificate of Analysis.

The Certificate of Analysis and/or Certificate of Origin must meet MicroBioLogics’ Component Specifications. The Lot-Specific Certificate of Analysis and/or Certificate of Origin must identify:

1. the animal species; and,
2. the country of origin.

Component Specifications.

When a production component contains an animal by-product, a Lot-Specific Certificate of Analysis and/or Certificate of Origin is requested from the vendor. Each Certificate of Analysis and/or Certificate of Origin is reviewed to ensure the component meets component acceptance criteria in order for the component to be used for the production of microorganisms.

Limitations of Warranty.

Should a “Lot-Specific Certificate of Animal Origin” be required from MicroBioLogics, please request this certificate from MicroBioLogics’ Technical Department at clinical@mbi2000.com or from the information stated above. The Certificate is dependent upon, and referenced to, the Certificate of Analysis and/or Certificate of Origin we received from our vendor containing information listing the animal species and country of origin; for the purpose of our customer’s concern regarding BSE (bovine spongiform encephalopathy). MicroBioLogics’ product is warranted to the extent and accuracy of the information provided by the vendor.

MicroBioLogics can not be held liable for a vendor’s misrepresentation or any errors of commission, or omission.

Submitted For the Record

Danette Then
MicroBioLogics
Executive Representative
Compliance Officer