

WUXI NEST BIOTECHNOLOGY CO.,LTD

Certificate of Compliance

Certified EN ISO13485: 2016

Product Number: 771204

Lot Number: 051324KC01

Product Name: Nest BioFactory 5 Chamber, Wide Mouth, TC, Sterile

Manufacture Date: 2024-05-13

Expiration Date: 2027-04

Materials:

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers.

Sterilization:

Products certified sterile have been validated for the proper E-Beam radiation dosage based on ISO 11137. This validation procedure is verified to insure all sterilized product receives adequate doses of E-Beam. Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6} .

BSE/TSE:

Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Non-Pyrogenic:

Products certified non-pyrogenic have been tested and have met the criteria established in the *Pharmacopoeia of China* (Ch.P). The acceptance level for product is ≤ 0.05 EU/ml.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of Cell Attachment and Growth utilizing an attachment-dependent mammalian cell line in a serum supplemented media, Attachment and Growth Performance.

RNase/DNase Testing:

The product has been tested and is free of any detectable RNase/DNase contamination.

Quality Control Testing:

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Test:

Visual Attributes:

Hydrophilic Test:

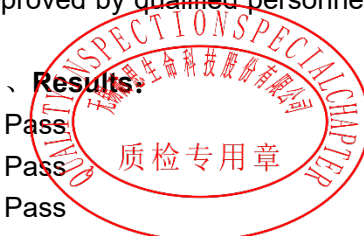
Leak Test:

Results:

Pass

Pass

Pass



Drawn: Jiang Meiqi

Approved: Li Ning

Released: He Yun

Date: 2024-05-23

Date: 2024-05-23

Date: 2024-05-23

NEST

TEL: (+86) 0510-68006788

FAX: (+86) 0510-68006788

No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi

<https://www.cell-nest.com>