

Certificate of Quality

REF

781061-25

LOT

B210134J

Product description: 384WF, PSC, HB, 150/CS

Following inspections were carried out and passed:

raw material	☒	passed
visual	☒	passed
physical	☒	passed

Free of detectable DNase/RNase/human DNA
Representative product was tested by Real-Time-PCR.

Detection limits:

DNase 1.3×10^{-8} Kunitz units
RNase 5.0×10^{-11} Kunitz units
hDNA 5 pg

Free of detectable endotoxins (pyrogens)
Representative product was tested according to the United States Pharmacopoeia (USP) Chapter <85>
Detection limit: 0.03 EU/ml

Binding Property

MICROLON® coefficient of variation < 5% (IgG ELISA / transmission measurement)
FLUOTRAC# coefficient of variation < 10% (IgG ELISA / fluorescence measurement)
LUMITRAC# coefficient of variation < 10% (IgG ELISA / luminescence measurement)

We hereby certify that our products were manufactured and tested in accordance with the following international standards and meet the required specifications:

ISO 11137 "Sterilization of health care products - Radiation"

We are certified according to the Quality System Standard ISO 9001 and ISO 13485.



2024-12-21

STERILESAL 10^{-3}

This certificate is valid for the above mentioned lot and has no validity if no lot number is provided.



Certificate creation date: 2021-01-27

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