

Certificate of Quality

REF

655077

LOT

E25043AT

Product description: MICROPLATE, 96 WELL, F-BOTTOM (CHIMNEY WELL),
BLACK, FLUOTRAC, HIGH BINDING, STERILE,
10 PCS./BAG

Following inspections were carried out and passed:

raw material	<input checked="" type="checkbox"/>	passed
visual	<input checked="" type="checkbox"/>	passed
physical	<input checked="" type="checkbox"/>	passed

Free of detectable DNase/RNase/human DNA
Representative product was tested by Real-Time-PCR.
Detection limits:
DNase 4.54 × 10⁻⁹ Kunitz units
RNase 1.0 × 10⁻⁹ Kunitz units
hDNA 2.7 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.



2029-04-01

STERILESAL 10⁻³

This certificate is valid for the above mentioned lot and has no validity if no lot number is provided. This document has been created digitally and is valid without a signature.



Certificate creation date: 2025-10-31

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