

## Certificate of Quality

**REF**

781061-25

**LOT**

B210139D

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

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  $1.3 \times 10^{-8}$  Kunitz units  
RNase  $5.0 \times 10^{-11}$  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.



2024-12-27

**STERILE**SAL  $10^{-3}$ 

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



Certificate creation date: 2021-02-02

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