

Certificate of Quality

REF

670180

LOT

E24093AY

Product description: ONEWELL PLATE, PS, 127,8/85,5 MM, LID, VENTS,
TC, STERILE, 8 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 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

Non-cytotoxic
Representative product was tested according to ISO 10993-5 and has been shown to be non-cytotoxic.

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

ISO 10993-5 "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity"

ISO 11137 "Sterilization of health care products - Radiation"

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



2028-09-08

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: 2025-03-20

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