

Certificate of Quality

REF

678108

LOT

E20023H6

Product description: CELLDISC, 8 LAYERS, 2.000 CM², PS, CLEAR, TC, STANDARD SCREW CAP RED, STERILE, SINGLE PACKED

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.



2023-11-06

STERILESAL 10⁻⁶

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



Certificate creation date: 2020-03-04

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