

Certificate of Quality

REF

122263

LOT

E19013N6

Product description: CRYO.S, 2 ML, PP, ROUND BOTTOM,
INTERNAL THREAD, NATURAL SCREW CAP,
WRITING AREA, STARFOOT, NATURAL, STERILE,
100 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.



2024-01-08

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



Certificate creation date: 2019-02-06

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