

## Certificate of Quality

**REF**

127263

**LOT**

E18053BV

Product description: CRYO.S, 4 ML, PP, ROUND BOTTOM,  
EXTERNAL THREAD, NATURAL SCREW CAP,  
WRITING AREA, STARFOOT, NATURAL, STERILE,  
50 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  $1.3 \times 10^{-8}$  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

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.



2023-05-01

**STERILE**SAL  $10^{-6}$ 

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



Certificate creation date: 2018-05-24

[www.gbo.com](http://www.gbo.com)