

Certificate of Quality



121279



E1807394

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

Following inspections were carried out and passed:

| raw material | X | passed |
|--------------|---|--------|
| visual | X | passed |
| physical | X | 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.



2023-06-24 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: 2018-10-09

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Austria: Greiner Bio-One GmbH, office@at.gbo.com I Belgium: Greiner Bio-One BVBA/SPRL, info@be.gbo.com I Brazil: Greiner Bio-One Brasil, office@br.gbo.com China: Greiner Bio-One Suns Co. Ltd., office@cn.gbo.com I Germany: Greiner Bio-One GmbH, info@de.gbo.com I France: Greiner Bio-One SAS, infos@fr.gbo.com Hungary: Greiner Bio-One Hungary Kft., office@hu.gbo.com I India: Greiner Bio-One India Pvt. Ltd, info@gboindia.com I Japan: Greiner Bio-One Co. Ltd., info@jp.gbo.com Netherlands: Greiner Bio-One B.V., info@nl.gbo.com I Switzerland: Greiner Bio-One Vacuette Schweiz GmbH, office@ch.gbo.com Thailand: Greiner Bio-One Thailand Ltd., office@th.gbo.com I UK: Greiner Bio-One Ltd., info@uk.gbo.com I USA: Greiner Bio-One North America Inc., info@us.gbo.com