

Quality Assurance Certificate

Sartolab® Bottle, 1000 mL

Order no. 180-25-----E
Use before 04/2030
Pore size N/A
Lot no. 502072328

This document is to verify that the designated product was manufactured by Sartorius according to a Quality Management System that is certified for compliance with current ISO 9001, ISO 13485 and ISO 14001.

Sartorius hereby declares that the designated product was manufactured to meet the current specifications for these products. Sartorius also declares that the designated products have been manufactured from approved materials of construction and comply with design and manufacturing documentation.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released for the following characteristics:

- Membrane integrity test
- Visual attributes
- Packaging

Sterilization

This product has been irradiated and dosimetrically released based upon ANSI/AAMI/ISO 11137 recommended practices.
Sterility Assurance Level: SAL 10^{-6}

Materials Toxicity

Fluid path component materials were tested and determined to be non-cytotoxic in accordance to ISO 10993.

Animal Origin

The product is derived from non-animal and/or non-human source materials or materials that are in accordance with the European Commission's "Note for guidance on minimizing the risk of transmitting animal encephalopathy agents via human and veterinary medicinal products" (EMA/410/01 Rev 3). The information provided is based on documentation that we have received from our suppliers.

Stem-Cell-Certified

The product has been successfully tested for use with human mesenchymal stem cells. A defined, serum-free medium was filtered through Sartolab® vacuum filtration units and used to culture cells over three passages and the results were compared to those obtained with unfiltered medium. No impact on cell growth and critical cell characteristics was observed for the filtered medium.

07.04.2025

This is an electronic document and valid without signature

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