

## Quality Assurance Certificate

**Sartobind® Rapid A Lab**  
Affinity Chromatography Unit  
Membrane Volume 0.5 mL

This product is developed, produced and distributed according to a Quality Management System that is certified for compliance with DIN/ISO 9001.

**Order no.** SBLRA025EL-1  
**Use before** 08 / 2025  
**Lot no.** 240064133

**This product has passed Sartorius' inhouse tests and thus meets Sartorius' stringent quality control standards.**

**Quality assurance tests:** This product is tested for binding capacity and flow rate.

**Specification:**

Product : Sartobind Rapid A Lab  
Flow rate :  $\geq 25$  ml/(min x 0.1 MPa) with PBS, RT  
Dynamic binding capacity at 10% breakthrough :  
 $\geq 35$  mg/mL matrix at 5 MV/min  
(MV : Membrane volume)  
(Reference protein : Polyclonal IgG)

**Biosafety:** The final product meets the requirements of the current ISO 10993-5 which is equivalent to the current United States Pharmacopoeia (USP) <87> Biological Reactivity Tests, in vitro.

**TSE-BSE Status:** Conforms to the European Guidance EMA/410/01 rev 3.

**SVHC status:** The product conforms to (EC) No. 1907/2006 (REACH).

**Pressure Stability:** This product is tested with a pressure hold test and can be operated up to 0.8 MPa (8 bar / 116 psi).

**Note:** This product is supplied as non-sterile. The membrane is stored in 20-24% ethanol.

2024-10-01

Date



Dr. Anna Vreemann  
Site Quality Manager

Manufactured by Sartorius Stedim Biotech GmbH  
37070 Goettingen, Germany

Phone +49.551.308.0  
Fax +49.551.308.3289

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