

# Certificate of Compliance for ISO 10993-5 test

**Test Item:** Sartobind® Rapid A Lab, 0.5 mL SBLRA025EL-1  
**Project:** STUY424AA0212-1  
**Supplier:** Sartorius Lab Instruments GmbH & Co. KG, Otto-Brenner-Str. 20,  
37079 Göttingen, Germany

**Studies performed:** The following study was performed for the test item listed above according to ISO 10993-1, ISO 10993-5 and ISO 10993-12.

***In vitro* Cytotoxicity Assay: Cell Growth Analysis via XTT-Staining and Grading Score Analysis (Eurofins Munich Study No.: STUGC24AA1796-2)**

The the test item was extracted under agitation for  $24 \pm 2$  h with cell culture medium and L929 cells were incubated for 24 - 26 h with the extract. The decrease in the activity of mitochondrial dehydrogenases of the individual cultures was then analysed as a measure for cytotoxicity and compared to those of the controls. Additionally, a grading score analysis was determined.

**Results:** **In this study under the given conditions no leachable substances were released in cytotoxic concentrations from the test item as confirmed by two different endpoints (XTT, Grading).**

**The biological test did not show significant findings, so this part of biocompatibility testing was fulfilled.**

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