

## 1. „Acute Dermal Irritation/Corrosion Study with Rabbits“

Execution of the study and preparation of the samples have been conducted according to the following norms and directives:

- ISO 10993-10:2002, „Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity“
- ISO 10993-12:1996, “Biological evaluation of medical devices – Part 12: Sample preparation and reference materials”
- “The OECD-Principles of Good Laboratory Practice”, OECD Environment Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No.1, Paris 1998

### Result:

**“Extracts of the test article “HyCeram” are not irritant to the skin in this study.”**

## 2. Acute Eye Irritation/Corrosion Study with Rabbits“

Execution of the study and preparation of the samples have been conducted according to the following norms and directives:

- ISO 10993-10:2002, „Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity“
- ISO 10993-12:1996, “Biological evaluation of medical devices – Part 12: Sample preparation and reference materials”
- “The OECD-Principles of Good Laboratory Practice”, OECD Environment Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No.1, Paris 1998

### Result:

**“Extracts of the test article “HyCeram” are not irritant to eyes in this study.”**

### 3. "Salmonella Typhimurium Reverse Mutation Test"

Execution of the study and preparation of the samples have been conducted according to the following norms and directives:

- OECD-guideline 471 and directive 2003/32/EC, part. B. 13/14 and ISO 10993-4:1992
- Preparation of the extracts of the test article was performed in accordance with ISO 10993-12:1996

#### Result:

**According to the results obtained in this study, extracts of "HyCeram" are non-mutagenic in the Ames test with strains TA97a, TA98, TA100, TA102 and TA1535 with and without an external metabolising system.**