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## Statement on Biocompatibility

The product **WACKER ELASTOSIL® R 4001/70** (now renamed **R Plus 4001/70 MH**) has been tested according to USP Class VI (acute systemic and intracutaneous toxicity, implantation) but not according to ISO 10993. These tests have only been carried out with **ELASTOSIL® R 4001/40 MH** (now renamed **R Plus 4001/40 MH**) which is that product of the **R Plus 4001** series having the lowest content of filler and which therefore can be considered as the worst case material referring to possible migration of hazardous compounds. **ELASTOSIL® R Plus 4001/40 MH** has passed the ISO 10993 tests on haemocompatibility, cytotoxicity, 90-day-implantation, skin irritation and sensitization and pyrogenicity tests without showing any adverse effects. We therefore firmly believe that the test results received with **ELASTOSIL® R 4001/40 MH** (renamed **R Plus 4001/40 MH**) are representative also for **R Plus 4001/70 MH**, which has passed the USP Class VI tests without showing any adverse effects.

Wacker-Chemie AG

Burghausen, November 24, 2011

Dr. C. Burger  
GB-S-IMS Manager Product Stewardship 1

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