



Confirmation of biocompatibility

The products **WACKER ELASTOSIL® LR 3003/30-80 A/B** have been tested according to USP Class VI but not according to ISO 10993. These tests have only been carried out with **ELASTOSIL® LR 3003/20 A/B** which is that product of the **LR 3003** 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. **LR 3003/20 A/B** has passed the ISO 10993 test series for haemocompatibility, cytotoxicity, 90-day-implantation, skin irritation and sensitization and pyrogenicity without showing any adverse effects. We therefore firmly believe that the ISO 10993 results received with **LR 3003/20 A/B** will be representative also for **LR 3003/30-80 A/B**, which have passed the USP Class VI tests (acute systemic and intracutaneous toxicity, implantation) without showing any adverse effects.

Wacker-Chemie AG

Burghausen, September 08, 2011

A handwritten signature in black ink, appearing to read "C. Burger", written over a horizontal line.

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

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