

Statement of Conformity

Sponsor : **Kraiburg TPE GmbH & Co.KG**
Friedrich-Schmidt-Strasse 2
D-84478 Waldkraiburg
Germany

Material : **TM 4 MED**
Reference report : **09-0575-N1**

This is to certify that the biological safety performed under ISO 17025 accreditation status, as indicated in the above referenced USP Class VI report, can be used as compliant results with the ISO 10993-10, tests for intracutaneous irritation and ISO 10993-11, tests for systemic toxicity.



Jos Bollen
Director Europe

Leuven, June 9th 2009