

MEDICA 2006

Protecting Patients & Manufacturers



To comply with legal requirements, a biological investigation for safety is required prior to CE labelling or accreditation for medical devices.

Key features of safety are assays of biocompatibility. **BMP Laboratory GmbH** (Aachen), one of a few laboratory facilities accredited with ISO 17025 and ISO 10993, carries out compatibility studies for medical devices.

BMP checks are carried out following ISO 10993 for blood, cell and tissue compatibility, genotoxicity and reproduction toxicity, acute and subchronic toxicity, carcinogenicity and irritation or sensitisation as well as local effects after implantation. Furthermore, BMP is able to assist in the development of applied strategies to result in achieving CE labelling as well as risk analysis for medical devices.

Since 2004, BMP is the first accredited laboratory for pathohistological and immunohistological examinations of explants and implants failure in accordance with ISO 10993-6.

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