

WACKER SILICONES HEALTH CARE POLICY

This Policy relates to the use of WACKER silicone products in the manufacture of materials and articles used for health care applications.

- We generally do not permit the use of our products for the following applications:
 - Breast implants
 - Direct injection of Silicone fluids or -emulsions into body tissue or blood (e.g. lubricants for syringes, intraocular fluids).
 - Use of Silicone fluids or emulsions in applications, where direct transfer into body tissue or blood is possible (e.g. application of creams or ointments onto open wounds) and / or in applications in contact with the genital mucosa (e.g. lubricants for condoms or sexual emollients). As a few Silicone elastomers (RTV, LSR, HTV) may also contain significant amounts of Silicone fluids, our customers should check with WACKER the conformity of the chosen WACKER product with this Policy for the respective application.
- We reserve the right to exclude and not to sell for selected applications. In general, we exclude the use of our products for long term applications defined as greater than 30 days (single or repeated use), however we reserve the right to take a case by case decision. For devices for contraceptive or reproductive use, we will also reserve the right to take a case by case decision. Our customers are required to inform us about any such intended use of our products before purchasing products for such applications from us.
- It is the responsibility of the customer to ensure that the curing and post curing conditions are suitable for his specific application.
- It is solely the responsibility of the customer to determine suitability of our products for the specific application and to comply with all applicable statutory, regulatory and health care industry requirements, reviews/approval processes, and/or standards – including the applicable provisions of the Federal Food, Drug and Cosmetic Act as amended, including the Safety Medical Devices Act of 1990 and any standards or regulations promulgated by the Food and Drug Administration as well as other similar governmental bodies, and the regulations issued under these laws before any WACKER product is used by the customer in any health care device or related application. Food and Pharma applications are subject to separate regulations and are not part of this policy.

- We require that our customers immediately inform us if they become aware of any concerns or problems found in connection with the use of our products in their health care applications.
- Specific conditions are stipulated in individual supply agreements.

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WACKER

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Integrated Management System certified according to ISO 9001 and ISO 14001.