

Wacker Chemie AG
Hanns-Seidel-Platz 4, 81737 München, Germany

Acknowledgement of the WACKER Health and Human Care Guidelines

Dear Customer:

Silicones are a major part of thousands of products we come in contact with every day. This remarkable family of materials has become even more vital to our quality of life. It is therefore of importance to Wacker Chemie AG to propose guidelines for the proper use of our products.

Silicones have been successfully employed for many years in medical devices and have saved thousands of lives in such applications. A comprehensive study of the medical literature indicates that appropriate silicone products are suitable for a large number of medical uses.

For healthcare applications a selected range of our silicone products have been evaluated for biocompatibility according to USP Class VI testing protocols. The results indicate that these products are biologically compatible for short term implant devices. However, it is the sole and exclusive responsibility of the customer to select Wacker Chemie AG products suitable for the intended purpose and to design, manufacture and sell the end products satisfying all applicable statutory, regulatory and industry requirements.

As a matter of clarification for our customers, Wacker Chemie AG. has developed the attached guidelines for the responsible participation in the healthcare market. We are confident that you will understand this position as a present and future supplier.

Yours sincerely,

Wacker Chemie AG

Dr. Walter Held
Senior Manager
Umweltmanagement/Product Stewardship

Registered Office: München, Germany
District Court: München HRB 159705
Executive Board:
Rudolf Staudigl (President)
Joachim Rauhut
Wilhelm Sittenthaler
Guido Willems
Supervisory Board Chairman:
Peter-Alexander Wacker

WACKER HEALTH CARE GUIDELINES

These guidelines relate to the use of Silicone products in the manufacture of medical devices.

We do not sanction the use of our products for and do not sell into long term implant applications defined as greater than 30 days.

In no case will we sanction the use of our products for the following applications:

- **Cosmetic reconstruction**
(e.g. plastic surgery, prosthetic devices)
- **Devices for gynecological or obstetric applications**
(e.g. pessaries, tampons, vaginal stents) except for diagnosis and monitoring and surgical instruments
- **Contraceptive or reproductive devices**
(e.g. condoms, condom lubricants, intrauterine devices, cervical caps)
- **Free injection** including the use of silicone fluids where they can be introduced directly into tissues, body cavities or blood (e.g. syringe lubricants, intraocular fluids).

We will sell our products for fabrication of most short term implant devices (less than 30 days) but we reserve the right to exclude selected applications.

For those applications defined as short term implant or where medical equipment results in tissue or blood contact, the Wacker Health Care products will be tested to USP Class VI testing requirements which include:

- Systemic toxicity
- Intracutaneous toxicity
- Muscle implantation

We will sell our products other than Health Care products for use in medical equipment where there is no contact with blood or tissue (e.g. skin contact only devices such as electrocardiographs) and these products will not necessarily be tested to USP Class VI requirements.

We will sell our non Health Care products for use in the manufacture of products used to manufacture certain dental devices with a contact duration of less than 24 hours. These products however, will not necessarily be tested to USP Class VI requirements.

It is the responsibility of the customer to adhere to the curing and post curing conditions as specified in our elastomer product technical brochures.

It is the customer's responsibility to determine material suitability for the specific application and to comply with all applicable statutory, regulatory and health care industry requirements and/or standards for testing, safety, efficacy and labeling requirements and to meet these requirements and/or standards - including the applicable provisions for the Federal Food, Drug and Cosmetic Act particularly as amended by the Safety Medical Devices Act of 1990, and the regulations issued under these laws before any Wacker product is used in any health care device or other application.

ACKNOWLEDGEMENT OF WACKER HEALTH CARE GUIDELINES

Please acknowledge within the next 14 days that you have read and understood our position and that you agree that it is your responsibility to determine the suitability of our material for your application.

You must be cognizant of our guidelines as described by having an officer of your company sign this document, and return it to the address below.

Company

Name

Address

Title/Position

Signature

Date

Return to:

Wacker Chemie AG
Dr. Walter Held
Hanns-Seidel-Platz 4
81737 München, Germany
Fax +49 89 6279-1703
walter.held@wacker.com