TRELLEBORG
SEALING SOLUTIONS

National and International Regulations and Standards for materials in contact with food and drugs

Standard authority	Regulations applicable to sealing and bearing materials
FDA	
The Food and Drug Administration (FDA) is a government agency within the U.S. Department of Health and Human Services and is responsible for enforcing the Federal Food, Drug, and Cosmetic Act to ensure the health and safety of consumers. It is mandatory that seal materials comply with the regulations issued by the FDA, when in contact with food or pharmaceuticals in processing or filling systems.	The 21 CFR part 177 consists of sections covering requirements for many different polymeric materials, such as section 2600 for rubber materials, in which "positive lists" describe the allowable substances and limitations as well as extraction tests. Extraction tests for finished rubber parts are carried out in n-hexane and distilled water. There are limitations set after seven hours and succeeding two hours in mg/ square inch.
EU	
The European Parliament and the council of the European Union have adopted a regulation that is valid in all member states of the European Union and does not require adoption by the governments of the individual member states.	The purpose of Regulation (EC) 1935/2004 is to ensure the effective functioning of the internal market and providing the basis for ensuring a high level of protection of human health. In Annex I it lists 17 groups of materials which may be covered by specific measures. Among them are metals and alloys, rubbers, plastics and silicones. The regulation requires among other things, Good Manufacturing Practice (GMP) for all food contact materials, a functioning tracking system and proper labeling. Appropriate documentation is required from all suppliers of food contact materials that declare compliance with the rules applicable to them. The rules for plastic materials are laid down in Directive 2002/72/EC and amendments.
3-A SSI	
3-A Sanitary Standards, Inc. (3-A SSI) is a not-for-profit U.S. organization that formulates sanitary standards and accepted practices for design, fabrication, installation and cleanability of dairy, food, beverage and pharmaceutical equipment or systems used to handle, process and package consumable products. Its goal is to protect consumable products from contamination and ensure that all product surfaces can be cleaned. A prerequisite for 3-A approval is that the seal material already fulfills the FDA requirements.	3-A SSI Standard number 18-03 'Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces'. There are four rubber classes, depending on the maximum exposure temperature of the material to product or sterilization. Class I is the highest standard.
	3-A SSI Standard 20-25, Multiple-Use Plastic Materials Used as Product Contact Surfaces.
USP	
The United States Pharmacopoeia (USP) is an independent, science-based public health organization. It is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements and other healthcare products manufactured and sold in the United States. The USP is considered one of the most technologically advanced and respected pharmacopoeias in the world.	There are two general chapters in the USP that describe test procedures and evaluation methods for polymeric materials or medical devices regarding their biological reactivity. USP Chapter <88>, in vivo: It classifies materials into six classes, where class VI requires the most extensive testing. The class designation is be accompanied by one of the following extraction temperatures 50°C, 70°C and 121°C/ 122°F, 158°F and 250°F, depending on the heat resistance of the material.
	USP Chapter <87>, in vitro: In this cytotoxicity test, extracts from the material go into a cell culture medium and undergo a growth inhibition test with mouse fibroblasts.
NSF	
NSF International is a not-for-profit, nongovernmental organization known worldwide for providing national standards and certification services in the areas of health and safety.	NSF/ANSI Standard 51 "Food equipment materials" is a certification of materials used in the construction of commercial food equipment. It requires a formulation review against the U.S. FDA regulations, laboratory testing and an audit at the production site. Annual renewal is mandatory. NSF/ANSI Standard 61 "Drinking water systems components Health effects." In order to comply to this standard, sealing materials have to undergo a third-party certification process which requires the formulation to be fully disclosed, toxicology tested and reviewed by the NSF organization.
BfR	
The German Federal Institute for Risk Assessment (Bundesamt für Risikobewertung, BfR) updates and elaborates recommendations within the framework of the "Federal Food and Feed Code" (LFGB.)	Recommendation XV, silicones describes in section III the requirements on silicone elastomers. Recommendation XXI, Commodities based on natural and synthetic rubber, contains formulation recommendations for rubber articles. Depending on the intended type of use, type of foodstuff (aqueous, acidic, fatty and alcoholic food) and contact time, simulants and procedures for migration testing are provided. There are four categories. Category 1 is the highest for long contact times of more than 24 hours and category 4 is the basic level for short contact times and/or small contact areas.
ISO	
ISO is the International Organization for Standardization. ISO developed standard 10993 for biological evaluation of medical devices.	ISO 10993-5: Biological evaluation of medical devices. Part 5: In vitro testing for cytotoxicity. This test is not only required by the medical device industry but also in some pharmaceutical or biotechnological processes where material toxicity with living cells is undesirable. The test method is the same as for USP <87> but displays the results differently.
French Ministry of Economy, Industry and Employment	
The Ministry prepares and executes government policy in many areas including consumer affairs and industry.	Order of November 9th, 1994: This national law contains positive lists and requires a series of laboratory tests. If a rubber material complies with this order, it can be marketed within the European Union in the sense of regulation (EC) 1935/2004, like materials complying with the German BfR recommendations.