High-Precision Ball Bearings

BIOCOMPATIBILITY - SAFE MATERIALS FOR OUR HEALTH

Since in applications such as surgical handpieces, blood pumps or other medical devices, ball bearing solutions from GRW have always been used on or even in the human body, where they contribute to the well-being of the human being, the safety and compatibility of the products and materials used is also a decisive criterion for GRW. In these extreme environments, we as a ball bearing manufacturer must ensure that our products function perfectly and do not damage the human body in the short or long term.

What began in the past with H1 approval for lubricants (approval for the food industry) has now been significantly extended by the proof of biocompatibility of a material for medical technology - a requirement that is also firmly anchored in the European Medical Device Directive (MDR), which has been mandatory since 2020.

DIN EN ISO 10993 with its 20 substandards regulates the testing of medical devices for biocompatibility, which can be understood as the biological harmlessness of the tested materials to any organisms. The two substandards DIN EN ISO 10993-5 and 10993-10 form the basic framework of a biocompatibility test, on which every test of medical devices is based on their biocompatibility and is supplemented by further substandards specific to the application.

The primary goal of a manufacturer of components for medical technology is generally to ensure absolutely reliable treatment of the patient, to provide maximum support for his recovery and to prevent direct negative effects on the patient during treatment. In addition, it must also be ensured that the human body does not develop any intolerance in long-term contact with a product or component. The latter applies primarily to products such as implants, which remain in the human body for months, years or even decades.

Over the last decades, medical research has identified more and more materials, lubricants or chemical elements in clinical studies that are suspected of causing direct or indirect damage to the human body or have even been clearly proven to do so. Often it has taken many years to prove this and to track down the pollutants. It is therefore all the more important, when developing new medical devices, to reverse the burden of proof and only use substances that are proven not to harm the body.

When developing new applications, this principle entails a large number of necessary tests which - depending on the risk class of the product - have to be passed before it is introduced to the market. The approval of medical devices on the market is therefore always a major hurdle for all manufacturers in the industry, and the requirements for the products are growing year by year.

At GRW, our customers can therefore choose from a range of currently 15 tested materials (1), consisting of ring steels, cage materials, lubricants, as well as covers, and assemble their biocompatible bearing from these. The materials were tested by an external testing laboratory with a certificate of compliance according GLP standards and DAkkS accreditation according to DIN EN ISO 17025:

- the cytotoxicity, i.e. the cell-damaging effect of the material (DIN EN ISO 10993-5:2009)
- the skin irritation on contact with the material (DIN EN ISO 10993-10:2014)

Like the requirements for medical products, the range of tested materials is constantly growing in order to provide customers with the best possible support in advance of market launch and to protect the health of all of us in the long term.