ISO 10993: Biological Evaluation of Medical Devices

The new Medical Device Regulation (MDR) increases the requirements for the safety of medical devices. As a result, much stricter requirements for the clinical evaluation of medical devices within the framework of the conformity assessment procedure will soon apply. Medical devices that come into direct or indirect contact with the human body must be biocompatible. The ISO 10993 series of standards provides an internationally harmonized system for assessing the biocompatibility of medical devices.

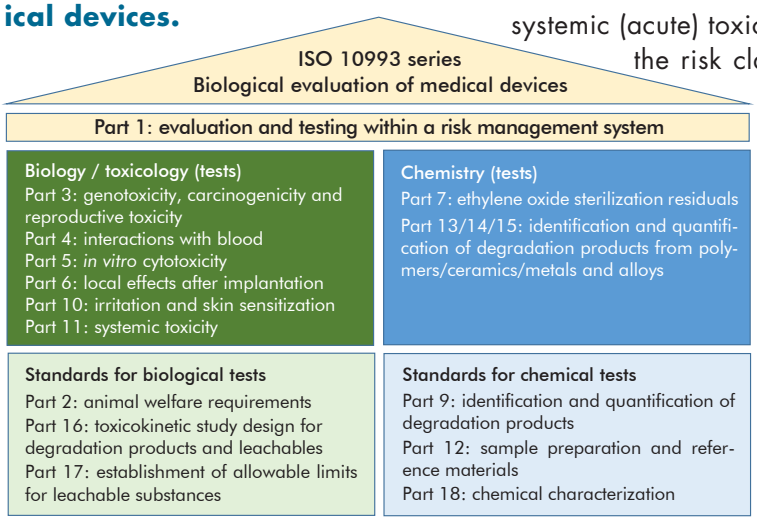

Figure 1: Overview of the ISO 10993 series of standards.

In a first step, the material must be identified and characterized and the chemical composition must be quantified (ISO 10993-18). This also includes degradation products (ISO 10993-13/14/15), leachables (ISO 10993-17), and residual impurities from the manufacturing process (ISO 10993-18). If the same material, i.e. with identical composition, the same manufacturing and sterilization processes, and with the same physical contact, is already commercially available as a medical device, no further biological tests for the assessment of biocompatibility must be carried out in accordance with ISO 10993-1. If this is not the case, however, toxicological, clinical or biological safety relevant data on the previously identified components of the medical device must be collected and evaluated.

According to ISO 10993-1, the existing safety data should be searched for and evaluated by means of a literature study before appropriate cell, animal or clinical studies are initiated to fill any gaps in the documentation. For a complete biological safety evaluation, the following toxicological data endpoints need to be taken into consideration: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic (acute) toxicity. Depending on the risk class of the medical device, which is a function of its invasiveness, as well as the duration and location of body contact, only a subset of these biological reactions need to be evaluated in a biological evaluation report. The RMS Foundation offers systematic, tailor-made literature studies of the relevant scientific literature on the safety of substances used in medical devices. Based on the resulting toxicological reports on the individual components, supplemented by internal safety information from the manufacturer (history of safe use, post-market surveillance), a biological evaluation report of the medical device is compiled in close cooperation with the manufacturer. If the identified safety data are not sufficient to assess the biocompatibility of the medical device, the biological reactions must be determined experimentally with new cell, animal or clinical studies.

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Our offers for the biological evaluation of medical devices:

- Qualitative and quantitative analysis of the chemical composition
- Qualitative and quantitative analysis of crystalline phases
- Qualitative and quantitative analysis of leachables and extractables
- Qualitative and quantitative analysis of potential degradation products
- Qualitative and quantitative analysis of residuals
- Scientific literature studies
- Biological evaluation reports

Discuss your questions with us! We are happy to advise you.

Contact for biocompatibility:

Marc Bohner
Phone +41 32 644 20 40
marc.bohner@rms-foundation.ch

More information as well as our service catalogue can be found on our website.

RMS Foundation has been certified according to ISO 9001 and is an ISO/IEC 17025 accredited laboratory type C.

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