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Biological Evaluation of Medical Devices

Ensuring safety before clinical use

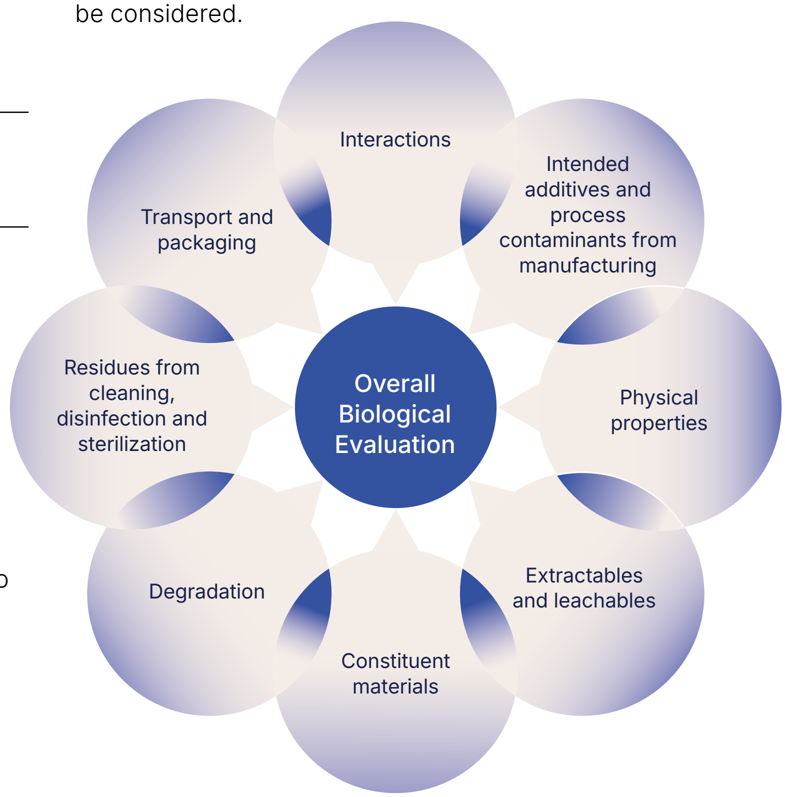
The design of safe medical devices begins with biocompatible materials which are physically suitable for the intended purpose of the medical device. The related evaluation of biological safety of medical devices is a critical milestone on the journey to CE marking and global market access.

Compliance with the corresponding General Safety and Performance Requirements is typically demonstrated by conducting a biological evaluation in accordance with:

- **ISO 10993** series of standards for medical device components in direct or indirect contact with the patient and / or user;
- **ISO 18562** series of standards for gas pathways incorporated into a medical device, which provide respiratory care or supply substances via the respiratory tract to a patient.

The latter is mostly used in conjunction with ISO 10993 since most of the medical devices with gas pathways combine components in direct contact. Since both series of standards sum up to 27 individual documents, a good point to start is the respective first standard in the series: ISO 10993-1 or ISO 18562-1. Both provide requirements but, more importantly, guidance and general principles on how to conduct a biological evaluation of medical devices.

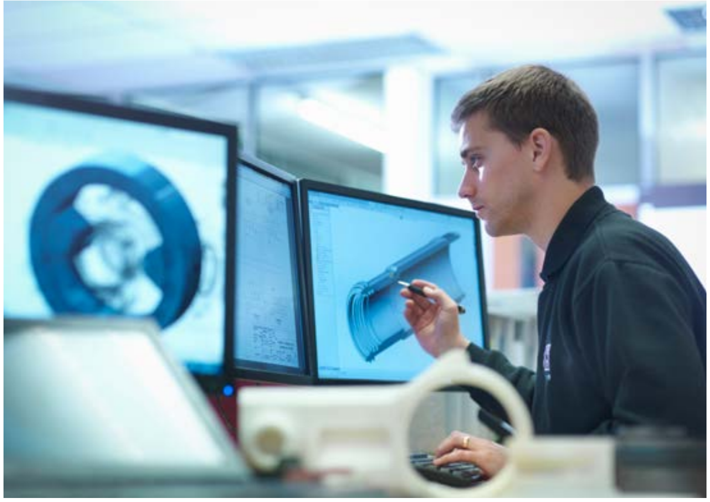
The primary goal is to identify biological risks and assess and evaluate them within a risk management system in accordance with ISO 14971. This involves assessing the biological reactions of the human body to the materials incorporated into the device in addition to residues from manufacturing aids, cleaning agents or sterilization. Furthermore, physical specifications of the product, potential degradation products, leachable substances, particles carried by gas flow, nanotoxicity and other factors need to be considered.



Related practical steps are the general categorization of a medical device based on their nature, frequency and duration of contact followed by a detailed material characterization. The underlying physical and chemical information is a basic requirement for the upcoming risk assessment. While the physical information helps to identify hazards associated with specifications such as shape, wear, friction, or surface of the medical device, the chemical information is used to determine both the qualitative and, where applicable, quantitative composition of the materials that may come into direct or indirect contact with the patient or user.

Thereby, the final product must be evaluated, which means that all manufacturing, cleaning, sterilization, packaging, transportation and other processes with all related residues (e.g., additives, dyes, process residues, contaminants, etc.) must be considered. These residues can be indirectly transferred to the patient or interact with the constituent material, which both may affect the biological safety of the medical device.

Once the material and substances have been sufficiently characterized, the biological effects are defined, which are to be addressed in the biological evaluation. These effects are closely associated with the identification of hazards in the context of risk analysis. Direct or indirect contact creates a corresponding hazardous situation, resulting in the associated risk, which must be assessed and evaluated as part of the biological evaluation.



The required information for both the material characterization as well as the risk evaluation of the biological effects is acquired via a stepwise approach. First, all available and relevant data will be gathered, analyzed and subjected to risk assessment. If there is a significant data gap, further data may be generated. Thereby, in favor of animal welfare, whenever analytical and *in vitro* testing is a valid option, it will be preferred over *in vivo* testing in animals.

NSF Services

Navigating the Regulation (EU) 2017/745 (MDR), ISO 10993, ISO 18562 as well as ISO 14971 can be overwhelming. NSF simplifies this process by guiding you through:

- ISO 10993-1 and / or ISO 18562-1 core principles and meet the requirements of the MDR
- the Risk Management Process according to ISO 14971 for the identification, evaluation and controlling of biological risks.

Our comprehensive support services:

Strategic Planning: development of a data-based strategy to demonstrate the biological safety of your medical device throughout its entire lifecycle.

Execution of the biological evaluation:

Application of a stepwise approach including

- Analysis of available data and gap-analysis
- Stepwise data gathering and analysis from literature and / or chemical databases
- Data-based evaluation of the need for additional biological safety testing
- Integration of the different elements of a biological evaluation into a risk management process
- Communication with certified test labs for a testing strategy tailored to your needs

Documentation support:

- Product-specific preparation and expert review of all required documentation (plans, reports, risk management file, etc.)
- Consistent inclusion of the outcome in relevant documents within the technical documentation

Specialized training programs:

- Delivering comprehensive remote or on-site trainings;
- Facilitating interactive workshops tailored to your team's specific needs;
- Training your staff in regulatory requirements and best practices regarding biological safety;
- Customizing educational materials for different stakeholder groups within your organization.

Ensure your medical devices meet the highest standards of biological safety and compliance. Contact us today to learn how we can support your journey to market.

Email us at info-medicaldevices@nsf.org or speak to our team on +49 40 66 87 88 100.

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