

Biocompatibility Services for Medical Devices

Biological evaluation of your
product in line with ISO 10993-1



**GET COMPLIANT
WITH THE NEWEST
STANDARDS**



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If you are manufacturing or supplying a medical device, you need to meet the regulatory obligations applicable in your target markets. A common requirement is the need to determine and minimise the biological risks of your product.

BIOLOGICAL EVALUATION

Evaluations carried out to determine the biological risks of medical devices are defined in the international standard series ISO 10993 and product-specific standards.

Since biological evaluation is a risk management activity, a Biological Evaluation Plan (BEP) is required, and this forms part of the Risk Management Plan. It is emphasized that simply planning to conduct testing against all of the aspects of biocompatibility identified in Table A.1 in Annex A of ISO 10993-1 does not meet the requirements (see Annex B.2.2).

OUR APPROACH

When planning a biological evaluation, we consider the specific requirements in your target markets.

We start with the categorisation of your medical devices and analyse the available physical and chemical information in detail, in order to evaluate and determine the steps required.

If chemical information is lacking, we will suggest performing chemical characterisation according to the current ISO 10993-18.

Based on these results, we will collect additional data using toxicological database and literature research. In many cases, sufficient data is already available and no or just a limited number of biological tests are required.

If further studies are necessary for the biological evaluation, we offer to plan, contract and monitor the laboratory studies using a laboratory of your or our choice to make sure the results meet your expectations and all relevant standards and guidelines.

Once the studies have been completed, we prepare a final report, which includes the toxicological risk assessment in line with ISO 10993-1 and ISO 14971, the discussion and evaluation of all results, and a comprehensive summary, including a clear statement with respect to biological safety.

YOUR BENEFITS

With our profound knowledge of the impact of various substances, our test selection will save you time and money and help to avoid unnecessary animal testing.

- Our biological evaluation plans include all information required to carry out the toxicological risk assessment and contain a detailed justification for waiving unnecessary tests.
- We have been working with numerous national and international testing laboratories and know which ones best suit your specific needs.
- Our biological evaluation plans and reports are prepared or reviewed by certified (DGPT) and registered (Eurotox) toxicologists to ensure the highest level of acceptance.

Please visit our website for more information or contact one of our experts at <https://scc-medical-devices.com/biological-evaluation-biocompatibility-iso-10993>

