



## *In vitro* biocompatibility testing of Medical Devices



The required biological endpoints for all medical devices in contact with patients are the “big three,” as defined by ISO 10993-1.

### **Cytotoxicity (ISO 10993-5)**

- Performed on 2D cell cultures to measure cell viability after exposure.
- MEM Elution Test (Qualitative) and MTT Test (Quantitative).

### **Irritation – skin and other tissues (ISO 10993-23)**

- Conducted on 3D reconstructed human epidermis (RhE) models.
- Additional irritation models are available for oral, ocular and other relevant tissues.

### **Skin Sensitization (ISO 10993-10)**

- Performed using GARD®skin Medical Device, based on genomics and machine learning.
- Supports testing of medical device extracts in polar and non polar extraction vehicles (ISO 10993-12).
- Aligned with OECD TG 442E and referenced in ISO 10993 10:2021 Annex C, with standard integration progressing.
- Optional: Quantitative potency assessment of sensitizers.

## Early adoption of NAMs offer advantages

### **In line with the 3Rs**

- Ethical
- Accurate
- Human relevant

### **Throughout the product life cycle**

- New devices and material selection
- Design changes
- Manufacturing and sterilization contaminants

### **Build internal readiness**

- Start building internal NAM relevant databases.
- Gain experience interpreting NAM based results.
- Strengthen weight of evidence in regulatory submissions.
- Reduce late stage regulatory risks.



## Scientific expertise and personal support *Top reasons customers test with us*



A SenzaGen Group Company

### Ensuring biological safety of medical devices

Biological evaluation is a key requirement for all medical devices with patient contact. Regulatory frameworks emphasize a risk based approach that combines chemical characterization, biocompatibility data and toxicological assessment to determine overall biological safety.

#### 1. Identify risks: GAP analysis and Biological Evaluation Plan (BEP)

A GAP analysis compares existing data to requirements in the ISO 10993 series, identifying missing information, potential biological safety concerns and the most efficient path to compliance. The BEP defines the testing strategy, rationale for endpoint inclusion/exclusion, and the planned approach to regulatory submission.

#### 2. Mitigate risks: *In vitro* biocompatibility testing aligned with the 3Rs

Biocompatibility evaluations typically include three core endpoints:

- Cytotoxicity: ISO 10993-5
- Irritation: ISO 10993-23
- Skin sensitization: ISO 10993-10

#### 3. Evaluate results: Biological Evaluation Report (BER)

The BER compiles test results, chemical characterization data, toxicological assessment, and literature data into a final evaluation of biological safety in accordance with ISO 10993-1 and regional requirements, ready for regulatory submission.

#### Relevant standards

- ISO 10993 standard series
- US FDA Guidance on ISO 10993-1 (2020)
- ISO 14971:2019 – Risk management
- EU Medical Device Regulation (MDR) 2017/745
- OECD TG 428 – Skin absorption (*in vitro*)

NAMs offer ethical, reliable and human-relevant alternatives to animal testing – supporting early material selection, design verification and regulatory submissions.