# *In Vitro* Biocompatibility Testing of Medical Devices

## According to ISO 10993

Our GLP-certified laboratories provide *in vitro* biocompatibility testing addressing the three endpoints that all medical devices are subjected to assess:

- Cytotoxicity: ISO 10993-5
- Irritation on skin and other epithelia: ISO 10993-23 using 3D reconstructed human tissues
- Skin sensitization: ISO 10993-10 using GARD®skin Medical Device with over 90% accuracy* and demonstrated applicability for use with the extraction vehicles saline and oil

## A highly accurate and ethical alternative to animal testing

**As part of the biological evaluation of finished medical devices**
To address the three endpoints that need to be evaluated for all medical devices following the 3Rs principle.

**As part of screening during the product life cycle**
For the selection of safe materials and to investigate toxicological hazards for production and sterilization contaminants during product development.

**Interested in potency information?**
For risk assessment of chemicals found during chemical characterization, GARD®skin Dose-Response can be used to provide quantitative potency information on skin sensitization.

*Johansson et al., Validation of the GARDskin assay for assessment of chemical skin sensitizers – ring trial results of predictive performance and reproducibility. Toxicological Sciences. May 17, 2019.

# Joint Expertise on Biological Evaluation of Medical Devices

SENZA GEN

VitroScreen

## SenzaGen and VitroScreen guide you through the comprehensive process of biological evaluation of medical devices:

**Product identification**
*In vitro* approaches to demonstrate the mechanism of action by using 3D reconstructed human tissues.

**Substance-based medical devices classification**
*In vitro* penetration, distribution and absorption studies to comply with MDR and Rule 21.

**Risk identification**
GAP analysis and Biological Evaluation Plan (BEP).

**Risk mitigation**
*In vitro* biocompatibility testing according to ISO 10993-1 and permeation, distribution and absorption studies according to OECD TG 428.

**Evaluation of results**
Biological Evaluation Report (BER), including toxicological risk assessment, safety margins calculation and biological testing interpretation.

## SERVICES SUMMARY

***In vitro* biocompatibility testing**
Our GLP-certified laboratories provide *in vitro* biocompatibility testing addressing the three endpoints that all medical devices are subjected to assess: cytotoxicity ISO 10993-5, irritation on skin and other epithelia according to ISO 10993-23, and skin sensitization according to ISO 10993-10 with GARD®.

**Mechanism of action on 3D reconstructed human tissues**
*In vitro* testing protocols on 3D reconstructed human tissues and pharmacological expert reports are provided to confirm that the medical device acts at the superficial level and the principal mechanism of action is physical, mechanical, or chemical and not linked to pharmacological, immunological, or metabolic effects.

***In vitro* penetration, distribution and absorption**
Protocols for penetration and absorption studies are established according to medical device class and type, formulation and intended use, and performed to quantify selected ingredients' penetration, absorption and local distribution. This data is used to support classification/re-classification of existing devices according to the MDR and the classification of new products that are applied to the skin, introduced into the body via body orifices, or with intended purpose in the stomach or lower gastrointestinal tract.

**Tailored consultancy services**
The *in vitro* testing and pharmaco-toxicological consultancy services provide expert advice during product development and/or to respond to regulatory requirements: for product identification as medical devices and medical device classification, risk identification, risk mitigation by *in vitro* testing and evaluation of results in the Biological Evaluation Report (BER).