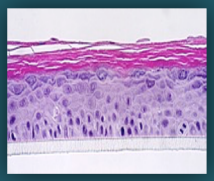
Evolution of dermal irritation assessment of MD and MD extracts

Rabbit intracutaneus or skin patch test ISO 10993-10 (**2010**)



RhE ISO 10993-23 (**2021**)

Salus Ante Omnia

Welcome ISO 10993-23!

VitroScreen supports the Medical Devices (MD) industry providing bio-compatibility studies for all MD classes on 3D human tissue models selected on the basis of the intended use of the device and the part of the body involved.

Since 2001 VitroScreen has been engaged in performing skin and mucosal tolerance studies for medical devices and topically applied products using 3D tissues and not 2D monolayers that suffer from poor biological relevance, low predictivity *vs* humans, and are not suitable to assess insoluble products/formulations.

Today we are happy to welcome ISO 10993-23 where the robustness, relevance and predictivity of 3D tissue models have been officially recognised and scientifically validated.

ICS › 11 › 11.100 › 11.100.20

ISO 10993-23

Biological evaluation of medical devices — Part 23: Tests for irritation

Furthermore, ISO 10993-23 supports the use of *in vitro* models other than epidermis to assess mucosal and corneal epithelium irritation potential. For this reason, ISO 10993-23 is the most innovative and disruptive guideline ever published and it will change the MD biocompatibility testing approach.

VitroScreen's expertise on the biological evaluation of topically applied products has a strong and acknowledged foothold:

- 2002 '*The importance of Multiple Endpoint Analysis (MEA) using reconstituted human tissue models for irritation and biocompatibility assay'* INVITOX - Proceedings Congress
- 2009 '*Multiple endpoint analysis of the 3D reconstituted corneal epithelium after treatment with benzalkonium chloride: early detection of toxic damage'* IOVS 50,4, 1644-1652
- 2010 '*In vitro assessment of skin and mucosae tolerance of cosmetic products'* M. Meloni et al., ESTIV-EUSAAT - Proceedings Congress
- 2016-2017 International Round Robin Study on MD extracts irritation potential on RhE
- 2018 '*Round robin study to evaluate the reconstructed human epidermis (RhE) model as an in vitro skin irritation test for detection of irritant activity in medical device extracts'* Toxicology in Vitro 50(2018) 439–449
- 2019 '*Medical devices biocompatibility assessment on HCE: Evidences of delayed cytotoxicity of preserved compared to preservative free eye drops*' Regulatory Toxicology and Pharmacology 106(2019) 81-89

Full papers available at https://www.vitroscreen.com/WEBVS/publications/