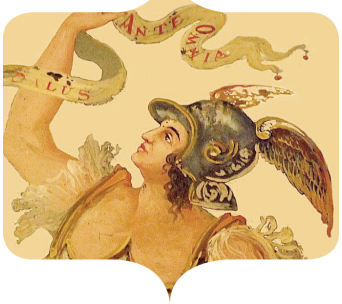
Towards the New Medical Device Regulation (MDR)



"Salus ante omnia" Farmacia Meloni - 1907

MEDICAL DEVICES

- The MDR is making its way through the final publication to replace the current Directive (93/42/EEC).
- The new Regulation addresses the importance of the criteria to achieve a **suitable risk-based classification** of **substance-based MD** taking into account the target of its action and the information on systemic absorption of the substance and its metabolism (Rule 21).
- The evaluation of MD can be performed by using **alternatives to animal testing:** *"**In vitro test** methods validated, reasonably and practically available, reliable and reproducible, shall be considered for use **in preference** to in vivo test." according to **recognised** current/valid best **laboratory/quality practices**, for example **GLP** or **ISO/IEC** 17025" (ISO 10993-1, 4° Edition, 2009).*
- VitroScreen is a reliable partner to support MD development and classification according to the MDR by providing customers with the best *in vitro* approach on 3D human tissue models.
- Quantitative and robust information on 3D human tissues are predictive for human response and can be used to overcome the limitations of standard cytotoxicity on cell monolayers, often resulting in an over prediction of cytotoxicity and a potential risk of misclassification.

ADVANTAGES of VitroScreen multiple endpoint analysis (MEA) on 3D human tissue models

Robust results are generated by testing the product in realistic doses and exposures guaranteing high content and reliable risk assessment, thus reducing the toxicological risks.

BIOCOMPATIBILITY

A robust body of evidences and not only the result of a single test is generated by performing the MEA approach. Irritation potential is assessed in realistic conditions allowing to underline any interference with tissue physiological homeostasis including barrier function properties and absence of systemic effects: this last is the most important requirement for MD classification.

EFFICACY

3D tissue models are **a must to define and quantify the MD mechanism of action** without pharmacological, immunological or metabolic mechanism. They represent a unique alternative before planning the clinical trial predicting the MD effects directly on body barriers.