



## **SBMD Qualification and Classification: Pre-clinical Approaches to Mechanism of Action**

**Milan, 9 FEBRUARY 2023**

Excelsior Hotel Gallia  
Piazza Duca D'Aosta, 9  
20124 Milano

### **Seminar Objective**

VitroScreen has been a pioneer in developing and proposing pre-clinical experimental protocols on 3D reconstructed human tissue models: they are currently applied to demonstrate the mechanism of action of SBMD and they are relevant to comply with the safety and efficacy requirements of the EU MDR 2017/745.

The seminar has the ambition to open a discussion on MDCG 2022-5 with stakeholders involved in Medical Devices (Health Authorities, Notified Bodies, Academia, Industry and ISO representative) analyzing the state of the art of scientific approaches to qualification and classification issues.

# Program

- 8.30 - 9.00**    **Registration**
- 9.00 - 9.15**    **Welcome**  
Marisa Meloni, *VitroScreen Founder and CEO*
- 9.15 - 9.30**    **Introduction to MDCG 2022-5  
and industry perspectives**  
Giulia Magri - *Confindustria DM*
- 9.30 - 10.15**    **Pre-clinical efficacy on 3D reconstructed  
tissue models: case studies**  
Paolo Buratti and Francesca Urso - *VitroScreen*
- 10.15 - 10.30**    **MDCG 2022-5: the qualification process**  
Maria Grazia Leone - *Ministero della Salute,  
Direzione generale dei dispositivi medici  
e del servizio farmaceutico*
- 10.30 - 11.00**    **Coffee break**
- 11.00 - 12.30**    **Open Discussion with Notified Bodies**  
Alessia Frabetti - *KIWA CERMET*,  
Chiara Novi - *TUV Rheinland Italia*,  
Alessandra Sepe - *Istituto Superiore di Sanità*
- 12.30 - 12.50**    **Looking for a common perspective**  
Alessandra Semenzato - *Dipartimento di Scienza  
del farmaco, Università degli studi di Padova*
- 12.50 - 13.10**    **Updates on ISO activities**  
Christian Pellevoisin - *Convenor of ISO Group 8  
Technical Committee 194*
- 13.10 - 13.30**    **Conclusion**
- 13.30 - 15.00**    **Networking Lunch**

## General information

The official language of the seminar will be Italian.  
Speakers' presentations will be supported by slides in English.  
Translation in English will be available for on-line foreign participants.

Registration details: registration in presence is limited to 100 participants and will close latest on January 31<sup>st</sup>.

### Payment

Registration fee: € 150,00 + VAT 22%

The quote include:

- English translation for on-line foreign participants
- Coffee break and Lunch

[CLICK HERE TO REGISTER](#)

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