



## **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

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

## 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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