RMD 2025 EUROPE

European Association of Authorised Representatives

The 9th EAAR Annual Conference on MEDICAL DEVICE REGULATIONS

24-25 February 2025

Brussels, Belgium

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Program Book

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Conference Venue

Sheraton Brussels Airport Hotel
Brussels International Airport, 1930, Brussels, Belgium
+32 2 710 80 00

Conference Hours

The Registration Desk will be open during the following times:

Monday, 24 February	08:00–18:00
Tuesday, 25 February	08:30–16:00

Participants Badge

Upon registration, you will receive your name badge. You are kindly requested to wear your name badge throughout the Conference.

Refreshments

Coffee and lunch will be served in the Exhibition Area taking place in the Foyer at the times indicated in the Conference Timetable.

Photography and Recording Privileges

No photographs, video recordings or audio recordings may be permitted in the sessions at this Conference unless otherwise authorized by the Conference Organizers.

Safety and Security

Please do not leave any bags or suitcases unattended at any time, whether inside or outside session halls. The Conference Organizers cannot accept liability for personal accidents or loss of/damage to private property of participants of **RMD2025**.

Congress Secretariat: info@bioevents-congress.com
Tel: US +1-857-400-0035 ; UK +44-203-051-4032

Monday, 24 February 2025

08:00-18:00	**Registration**
09:20-09:30	**Conference Opening & Welcome** ***Ludger Möller*** *| Conference Chair*
Session 1: Current State of Play in the Implementation of MDR & What's Coming Next	
09:30-10:00	**State of the Play with More In-Depth Upcoming Policies** ***Nada Alkhayat,*** *Policy Officer at European Commission, Belgium*
10:00-10:30	**Proposal for the Revision of the EU MDR** ***Erik Vollebregt,*** *Partner, Axon Lawyers, The Netherlands*
10:30-11:00	**Position of MTE on the Proposal to Revise EU MDR** ***Petra Zoellner,*** *Regulatory Affairs (IVDR & MDR) Director, MedTech Europe, Belgium*
11:00-11:30	**Coffee Break, Networking and Visit the Exhibition** One-to-One Meetings (11:00-11:20)
Session 2: Notified Bodies - MDR	
11:30-12:10	**Technical Documentation Compilation, Example of SaMD or Legacy Devices** ***Virginie Siloret,*** *Global Medical Devices Certification Manager, SGS, France*
12:10-12:50	**MDR Journey: Challenges, Opportunities and Recommendations** ***Bassil Akra,*** *CEO and President of AKRA TEAM, Germany*
12:50-13:00	**Discussion / Q&A**
13:00-14:00	**Lunch Break, Networking and Visit the Exhibition** One-to-One Meetings (13:00-13:30)
Session 3: State of Play and NB Expectations - IVD	
14:00-14:40	**State of Play** ***Olga Tkachenko,*** *Policy Officer, European Commission, Belgium*

14:40-15:20	**How to Prepare for your IVDR Transition for Successful CE-Marking** ***Daphne Hessels,*** *Project Manager IVD and Medical Devices, DEKRA Certification, Netherlands*
15:20-15:30	**Discussion / Q&A**
15:30-16:00	**Coffee Break, Networking and Visit the Exhibition** One-to-One Meetings (15:30-15:50)
16:00-17:00 **Session 4:** Supply Chain Roundtable (Importers, Distributors)	
	How they Implemented MDR/IVDR Requirements ***Volker Lücker,*** *Editor, Deutscher Apotheker Verlag, Germany*
	BSI on Article 16 ***Albert Roossien,*** *Regulatory Lead at Medical Devices Notified Body BSI Group The Netherlands*
Session 5: Manufacturer Success Story	
17:00-17:30	**Success Story in Implementing MDR** ***Giulia Girola,*** *Regulatory Affairs Specialist, Materialise, Belgium*
17:30-18:00	**Success Story in Implementing IVDR** ***Ilinca Visanoiu,*** *Regulatory Affairs Manager MRC Holland, Netherlands*
18:00	**Networking Cocktail**

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Tuesday, 25 February 2025

08:30-16:00	**Registration**
08:50-09:00	**Welcome Session** ***Ludger Möller*** *| Conference Chair*
Session 6: Digital Era & Medical Devices	
09:00-09:30	**Bringing the EU AI Act to the Boardroom** ***Koen Cobbaert,*** *Senior Manager – Quality, Standards and Regulations at Philips, Belgium*
09:30-10:00	**AI Act** ***Nada Alkhayat,*** *Policy Officer at European Commission, Belgium*
10:00-10:30	**Authorized Representive Under AI Act** ***Ludger Möller,*** *EAAR Chairman, President, MDSS GmbH, Germany*
10:30-11:00	**Coffee Break, Networking and Visit the Exhibition** One-to-One Meetings (10:30-10:50)
Session 7: Vigilance & PMS	
11:00-11:30	**Eudamed Vigilance Module, Testing from a CA Perspective** ***Marcel Schijf,*** *Medical Technology Health and Youth Care Inspectorate, Ministry of Health, Welfare and Sport, Netherlands*
Session 8: Clinical Data Requirements and Clinical Investigations	
11:30-11:50	**Strategic Approaches to Clinical Data Requirements in the EU and US** ***Maria Donawa, M.D.,*** *President, Donawa Lifescience Consulting, Italy*
11:50-12:10	**The Challenges of Navigating Performance Study Applications/Notifications in Europe and their Impact on Pharma Clinical Trials** ***Kirsten Van Garsse,*** *Regulatory Affairs Manager & Director Authorized Representative Operations, Qarad, Belgium*

12:10-12:30	**Is it a Drug or a Device? How to Use the Authorities to Find the Best Possible Clinical Investigation Design and Pathway** ***Søren Underbjerg,*** *Team Lead Clinical Development and Market Access, Qmed, Denmark*
12:30-14:00	**Lunch Break, Networking and Visit the Exhibition** One-to-One Meetings (12:30-13:00)
Session 9: UK & Switzerland	
14:00-14:30	**Swiss, FDA Approvals** ***Hasmik Kirakosyan,*** *Consultant, MDSS, Germany*
14:30-15:00	**UKRPA on UK State of Play, Recognition of Devices** ***Mika Reinikainen,*** *UKRPA Chairman, Managing Director, Abnovo, UK*
15:00-15:30	**Q&A for all Speakers and Conference Closing Remarks**
15:30-16:00	**End Coffee Break, Networking and Visit the Exhibition** One-to-One Meetings (15:30-15:50)

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The 9th EAAR Annual Conference on Medical Device Regulations (RMD2025) would like to express its gratitude and acknowledge the following company for its generous support of the Conference.

Exhibitor:

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY