RMD 2023 EUROPE

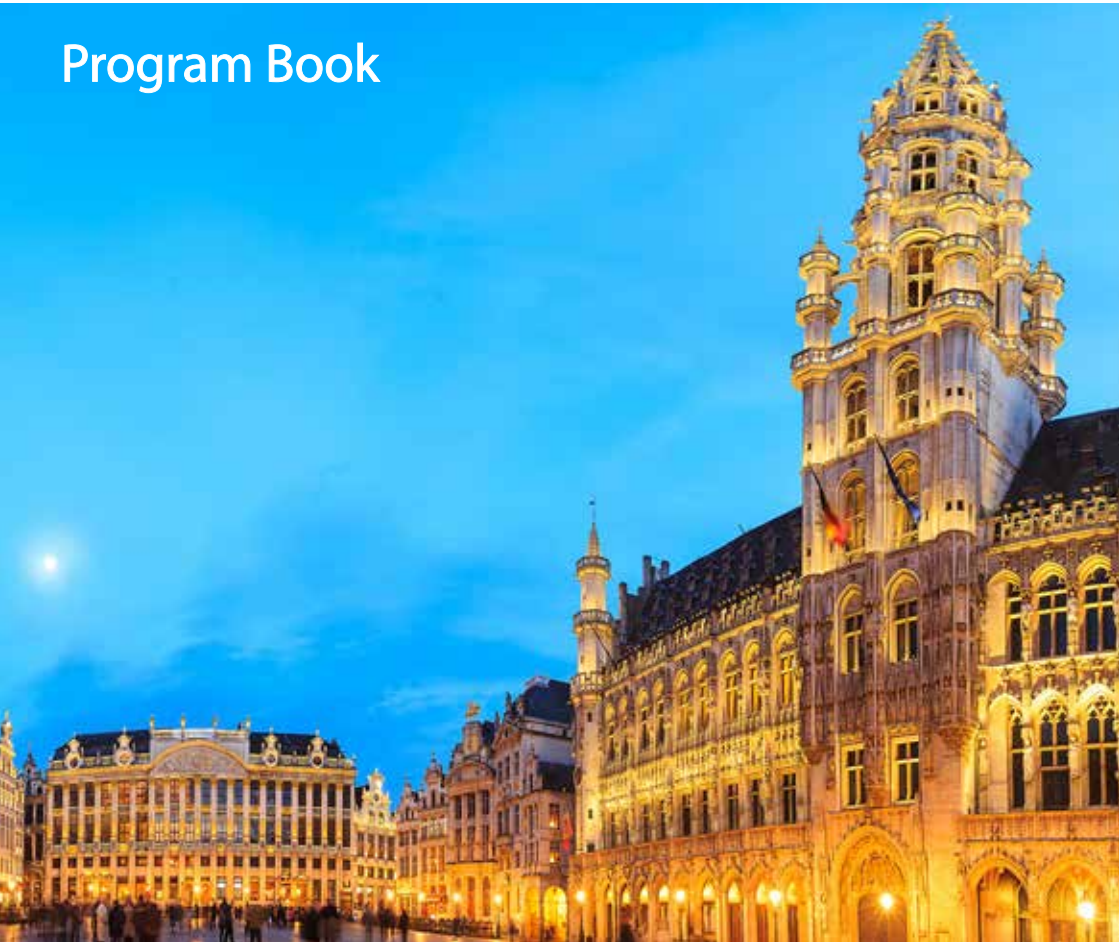
The 7th EAAR Annual Conference on

NEW MEDICAL DEVICE REGULATIONS

2-3 February 2023 | Brussels, Belgium

European Association of Authorised Representatives

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:

Thursday, 2 February	08:00–17:30
Friday, 3 February	08:30–17:40

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 RMD2023.

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

Thursday, 2 February 2023

08:00-17:30 **Registration**

08:50-09:00 **Welcome and Opening Remarks**
Members of the EAAR Executive Committee:
Ludger Möller, *EAAR Chair*
Gideon Elkayam, *EAAR Treasurer*

Session 1: Current State of Play in the Implementation of MDR & IVDR

09:00-09:30 **State of Play**
Hanim Yassin, *Policy Officer – SNE, Unit D.3 – Medical Devices, DG SANTE, European Commission*

09:30-10:00 **MDR: A Success Or A Flawed System That Has Damaged EU Medtech?**
Amanda Maxwell, *Regulatory Affairs Editor, Medtech Insight, Informa Healthcare, UK*

10:00-10:30 **Latest Developments on MDR**
Dario Pirovano, *Senior Regulatory Affairs Adviser, MedTech Europe, Belgium*

10:30-11:00 **Coffee Break, Networking and Visit the Exhibition**

Session 2: MDR & IVDR: Market Surveillance by Competent Authorities

11:00-11:30 **State of Play with Focus on Market Surveillance**
Thierry Sirdey, *Co-chair of Competent Authorities for Medical Device Committee, France*

11:30-12:00 **Belgium: Derogation process under MDR Art. 59 and Art. 97**
Alexandre Jauniaux, *Head of Division Medical Devices, FAMHP, Belgium*

12:00-12:30 **National Requirements Additional to MDR - A Case Study: SPAIN**
Claire M. Murphy, *EAAR Member of the Board, Consulting Partner, Tecno-med Ingenieros, SL, Spain*

12:30-13:30 **Lunch Break, Networking and Visit the Exhibition**

Session 3: Notified Bodies: Availability and Expectations

13:30-14:00 **Action Plan to Increase NBs Resources and Availability / Points of Attention for Non-EU Manufacturers**
Françoise Schlemmer, *Team-NB Director (Medical Devices Notified Bodies Association), Belgium*

14:00-14:30	**Current State of Play and Expectations from Manufacturers** ***Virginie Siloret,*** *Global Medical Devices Certification Manager, SGS Belgium NV*
14:30-15:00	**Will the EU Healthcare System Start Suffering from May 2024?** ***Bassil Akra,*** *CEO and Owner of AKRA TEAM GmbH, Germany*
15:00-15:30	**Coffee Break, Networking and Visit the Exhibition**

Session 4: Impacts of AI and Digital Innovations on Medical Devices

15:30-16:00	**Artificial Intelligence and Effect on MDR/IVDR and Potential Conflicts** ***Koen Cobbaert,*** *Senior Manager – Quality, Standards and Regulations at Philips, Belgium*
16:00-16:30	**Medical Devices Apps Compliance – Software as a Medical Device or IVD** ***Robert Ginsberg,*** *EAAR Member of the Board, Chairman of the Board, QAdvis, Sweden*
16:30-17:00	**Online/Distance Sales and Implications for Selling Medical Devices to the End User** ***Erik Vollebregt,*** *Partner, Axon Lawyers, The Netherlands*
17:00-17:30	**Panel Discussion / Q&A with all speakers of the day**
17:30	**End of Day One**

Friday, 3 February 2023

08:30-17:40	**Registration**

Session 5: EUDAMED, Person Responsible for Regulatory Compliance (PRRC) and Standardisation

09:00-09:20	**EUDAMED - Deadlines, Registration Process, Role of Authorised Representative** ***Ajda Mihelcic,*** *EAAR Secretary; Manager of Publications dept., PA Unit Obelis, Belgium*
09:20-09:40	**Practical Aspects for a Person Responsible for Regulatory Compliance within a Manufacturer** ***Ronald Boumans,*** *TEAM-PRRC, The Netherlands*
09:40-10:00	**Person Responsible for Regulatory Compliance within Authorised Representative** ***Patrick Pille,*** *Consultant, MDSS, Germany*

10:00-10:30	**Standards and Harmonisation Process. Latest Development- How to Act in Case of Absence of Harmonised Standards** ***Nils-Åke Lindberg,*** *Member of the Board, EAAR; Founder of QAdvis, Sweden*
10:30-11:00	**Coffee Break, Networking and Visit the Exhibition**
Session 6: Clinical and Post-Market Surveillance: Practical Aspects	
11:00-11:30	**MDR Clinical & IVDR Performance Evaluation** ***Helene Quie,*** *Member of the Board, EAAR, CEO, QMed Consulting, Denmark*
11:30-12:00	**EU IVDR Conformity Assessments; Current State of Play at the Notified Bodies** ***Alex Laan,*** *Head of IVDs at BSI, Netherlands*
12:00-12:30	**Post-Market Surveillance from a Practical Perspective & Vigilance and Related Medical Device Coordination Group (MDCG) Guidance Documents** ***Ludger Möller,*** *EAAR Chairman, President, Medical Device Safety Service, Germany*
12:30-13:30	**Lunch Break, Networking and Visit the Exhibition**
Session 7: UK Roundtable	
13:30-13:50	**General Overview of Future UK Law by MHRA** ***Rob Higgins,*** *Senior Regulatory Affairs Specialist, Medicines and Healthcare Products Regulatory Agency (MHRA), UK*
13:50-14:10	**UK Responsible Person Association (UKRPA) Perspective on the Future UK Law** ***Mika Reinikainen,*** *UKRPA Chairman, Managing Director, Abnovo, UK*
14:10-14:30	**Lessons Learnt for UKCA Marking** ***Vishal Thakker,*** *Head of UK Approved Body & Senior Regulatory Lead, Regulatory Services (Medical Devices) BSI UK, UK*
14:30-15:00	**Discussion | Q&A**
15:00-15:30	**Coffee Break, Networking and Visit the Exhibition**
Session 8: CH Roundtable and IVDR	
15:30-15:50	**Solutions on Implementing IVDR, Including Performance Evaluation of Legacy Devices** ***Maurizio Suppo,*** *Member of the Board, EAAR, Co-owner & Principal Consultant, Qarad, Belgium*

15:50-16:10	**Pitfalls of the Third County Status of Switzerland to the EU: Impact on IVDs and Medical Devices** ***Daniel Delfosse,*** *Head of Regulation & Innovation Member of the Executive Board, Swiss MedTech, Switzerland*
16:10-16:30	**Switzerland and EU: Impact on IVDs and Medical Devices (Pitfalls)** ***Eric Klasen,*** *CEO, Obelis GmbH, Switzerland*
16:30-17:00	**Discussion | Q&A**
17:00-17:30	**Panel Discussion / Q&A with all Speakers of the day**
17:30-17:40	**Conference Closing Remarks** ***Ludger Möller,*** *EAAR Chair*
17:40	**End of Conference**

7th EAAR Annual Conference on New Medical Device Regulations (RMD2023) would like to express its gratitude and acknowledge the following companies and organizations for their generous support of the Conference.

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- Consultancy MDR/IVDR (Regulation (EU) 2017/745 and Regulation (EU) 2017/746)
- Technical Files Preparation & QMS

COSMETICS

- Consultancy Regulation (EC) 1223/2009
- PIF (Product Information File) Preparation

QUALITY & COMPLIANCE

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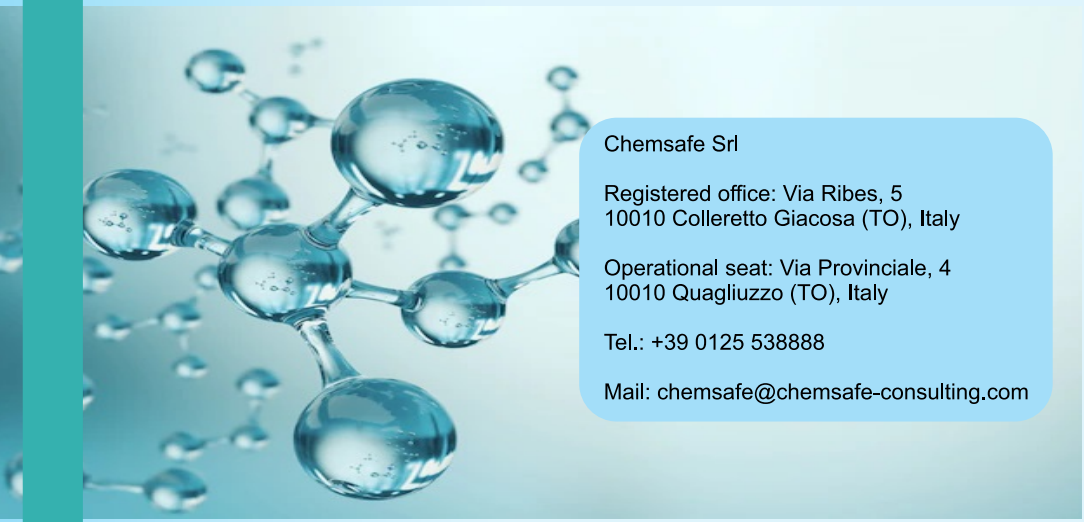

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