

## RAPS SWITZERLAND CHAPTER EVENT

Friday, May 18, 2018 at 13:30 - IV-Stelle Kanton Bern, Scheibenstrasse 70, 3001 Bern  
**Medical Devices - MDR / IVDR - First experiences – focus: Technical Documentation**

### Organizing Committee:

**Michael Maier:** RAPS Switzerland Chapter – VP, Head Medical Devices;  
Affiliation: Medidee Services SA, Lausanne

**Ary Saaman:** RAPS Switzerland Chapter – Executive Secretary,  
Affiliation: Debiotech SA, Lausanne

**Claudia Solimeo:** RAPS Switzerland Chapter – Head IVD;  
Affiliation: TECAN AG

**Elena Kyriacou:** RAPS Switzerland Chapter – Head Communication;  
Affiliation: ELEMED AG

**Alain Dransart:** RAPS Switzerland Chapter – Deputy Secretary – Head Active Implants  
Affiliation: Aleva Neurotherapeutics SA

### Conference Chair: Claudia Solimeo – RAPS Switzerland Chapter)

13h30 Registration

14h00 Chapter News – Gautam Maitra / Ary Saaman (News about Switzerland Chapter, how to get member in RAPS Switzerland Chapter, how to get involved) – 15 mins

14h15 Outlook RAPS Switzerland Chapter events 2018 – Michael Maier – 10 mins

14h25 Presentation of the speakers / subjects – Claudia Solimeo

### Technical Documentation under MDR / IVDR

14h30 Legacy Products – Steps to get Technical Documentation ready for conformity assessment under MDR / IVDR – Dr. Jurjen Zoethout, Medidee - 35 mins + Q&A

15h15 Technical Documentation under the MDR – Dr. Itoro Udofia, Head of Notified Body for UL International - 35 mins + Q&A

16h00 Short break

### Implementation MDR / IVDR - status

16h30 Status review – Implementation of MDR / IVDR – Peter Studer, Swiss Medtech – 35 mins + Q&A

17h15 Closing words – Dr. Claudia Solimeo, Michael Maier, Ary Saaman

17h30 Aperó light – Networking (End ca. 18h30)

**Date / time:** Friday May 18, 2018; 13h30 – 18h30

**Inscription:** mandatory prior venue until May 15, 2018 – by email to [ary.saaman@raps-switzerland.ch](mailto:ary.saaman@raps-switzerland.ch)

**Subscription fees:**

- RAPS Swiss Chapter Members 70 CHF
- RAPS Members 100 CHF
- Non-members 150 CHF (per invoice upfront or cash on site for late birds)

**Location:** IV-Stelle Kanton Bern, Scheibenstrasse 70, 3001 Bern

**Attention:** This event is limited to 70 Participants, first come, first served