

AGENDA

MEDICAL DEVICES SESSION 13 DECEMBER 2018

De Montil - Moortelstraat 8, 1790 Affligem

All slides and the presentations will be in English

Programme and Speakers:

13:00 Session introduction Annabelle Bruyndonckx, BRAS Education Group

A. Industry perspective

13.05 – 13.25 Medical Devices: Priorities for the next legislature
Mamix Denys – Director beMedTech

B. EU-Medical Devices Regulations (MDR-IVDR)

13.25 – 14.25 Placing medical device Class I and Custom made on the market under the regulation
Katrien Martens - Federal Agency for Medicines and Health Products

14.25 – 14.40 Reprocessing of single use devices – State of play
Richard Van den Broeck - Federal Agency for Medicines and Health Products

14.40 – 14.55 Impact of the Regulation on clinical investigations
Steve Eglem - Federal Agency for Medicines and Health Products

C. Recent developments at the Belgian level

14.55 – 15.25 Reorganization of the DG Inspection
Katrien Marten Federal Agency for Medicines and Health Products

15.25 – 15.55 Coffee break

15.55 – 16.05 New distribution channel for medical devices and medical devices campaign
Katrien Martens & Alexandre Jauniaux - Federal Agency for Medicines and Health Products

16.05 – 16.35 Service and technologies home assistance
Richard Van den Broeck - Federal Agency for Medicines and Health Products

16.35 – 16.50 Web applications for actors related to medical devices
Alexandre Jauniaux - Federal Agency for Medicines and Health Products

D. EU-Medical Devices Regulations (MDR-IVDR)

16.50- 17.20 Recast – state of play
Valérie Nys - Federal Agency for Medicines and Health Products

17.20 Questions & Answers

17.45 End of session – Ann Osselaere

Registrations through our website. (www.bras-org.be)

For registration you click on the line of the session in “Future courses and events” on the Home Page and then sign up. If you are not yet registered on the website you will be asked to do so. The system will send you a confirmation of registration with payment modalities by return mail.

If you need more assistance please contact Brigitte at bras@bras-org.be or call her on 02.757 06 29.

Fees: BRAS member **150€** - Non-BRAS member **350€**

It is understood, to be admitted to the session, that the fees have been pre-paid. **In case of cancellation after 5 December 2018 or no-show, the fees are due and will be invoiced.**