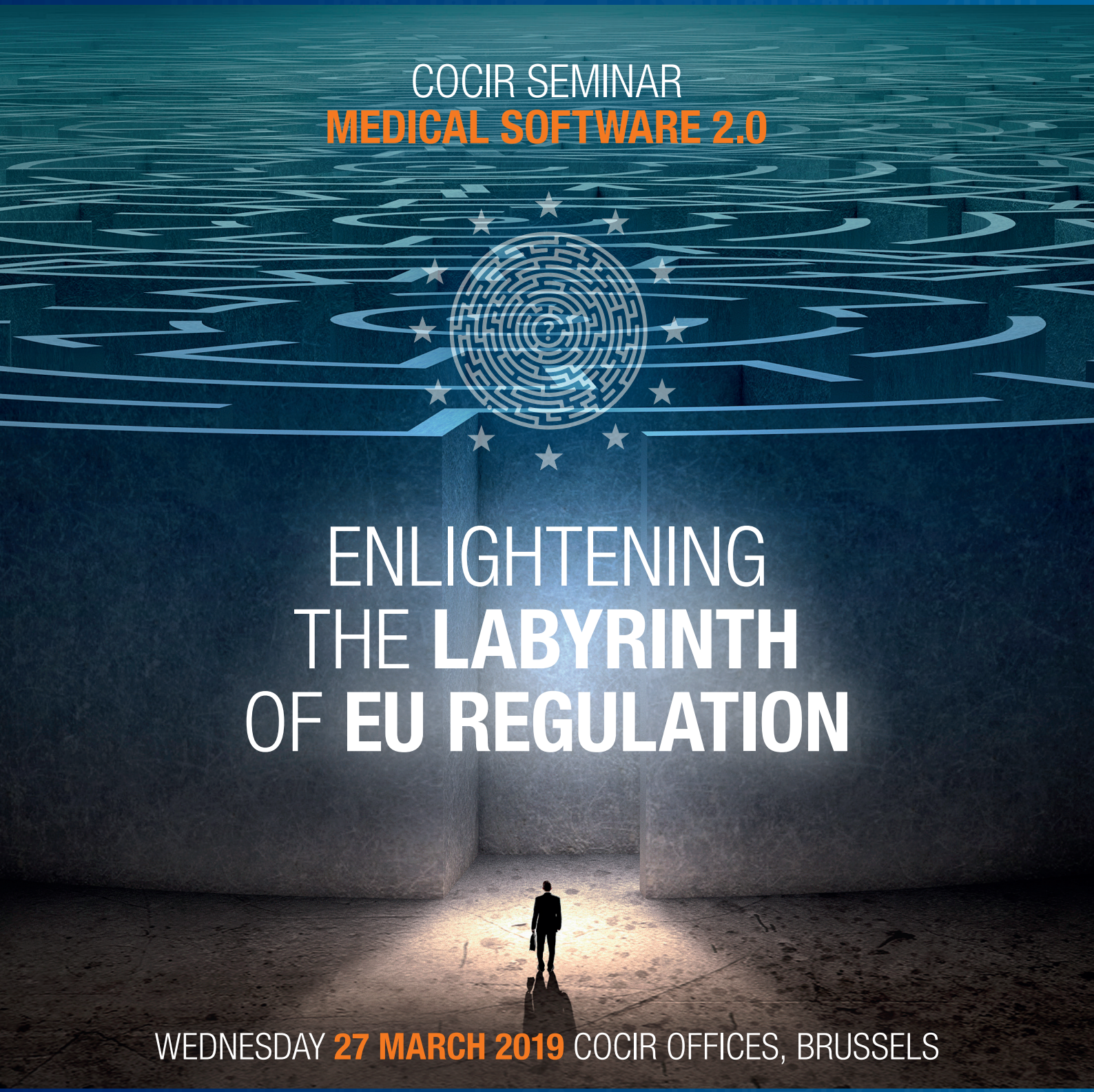
COCIR SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR SEMINAR

MEDICAL SOFTWARE 2.0



ENLIGHTENING THE LABYRINTH OF EU REGULATION

WEDNESDAY **27 MARCH 2019** COCIR OFFICES, BRUSSELS

BENEFITS OF ATTENDING THIS SEMINAR:

- Understand what software is regulated by MDR and how it is classified
- Receive guidance for the clinical evaluation of software
- Learn about the latest developments for cybersecurity
- Discuss the implications of the MDR for machine-learning software

PRICE

250€ PP
60€ PP (SME)
FREE FOR COCIR MEMBERS, NOTIFIED BODIES AND REGULATORS

REGISTER HERE

WHO SHOULD ATTEND

This seminar is primarily intended for industry, including SMEs, and for Notified Bodies, with an interest in software for healthcare purposes. Regulators will be welcome as well.

DRAFT PROGRAMME

Following on the successful first edition of our medical software seminar in June 2018, COCIR invites you another time to a deep dive into the challenges that the Medical Device Regulation poses especially for software. This is an excellent opportunity to gain the latest insights into on-going discussions on software requirements as the Date of Application is coming closer. Leading experts in the field will explain what you need to know to place your medical software on the market after May 2020. This time, the focus will be on software qualification & classification, clinical evaluation, cybersecurity and the specific challenges facing machine-learning software.

09:30	WELCOME COFFEE
10:00	**WELCOME** & **INTRODUCTION**
10:05	SESSION 1 **QUALIFICATION & CLASSIFICATION** The new guidance on classification of software under the MDR will be presented. In addition, industry experts will outline how the guidance will be used in the field and what the remaining open questions and next steps are.
11:15	SESSION 2 **CLINICAL EVALUATION** With the on-going development of guidance on clinical evaluation of software, we will address the burning questions that companies are asking in this area. Latest information on regulators' understanding will be provided as well as what industry is doing in practice
12:30	LUNCH BREAK
13:30	SESSION 3 **CYBERSECURITY** We will provide insights into key concepts for cybersecurity of medical devices and applicable legislation, including the NIS Directive, the new certification framework, and links with GDPR. As interpretation of the security requirements under the MDR is advancing, the focus lies on the related developing guidance at European and national levels
14:30	COFFEE BREAK
14:45	SESSION 4 **MACHINE LEARNING SOFTWARE** Machine Learning Software is facing unique challenges under the Medical Device Regulation. We will help to further understand this concept, the existing industry practices and standards as well as regulatory requirements and how to address them
15:55	**CONCLUDING REMARKS**
16:00	END

REGISTRATION
https://www.cocir.org/index.php?id=306