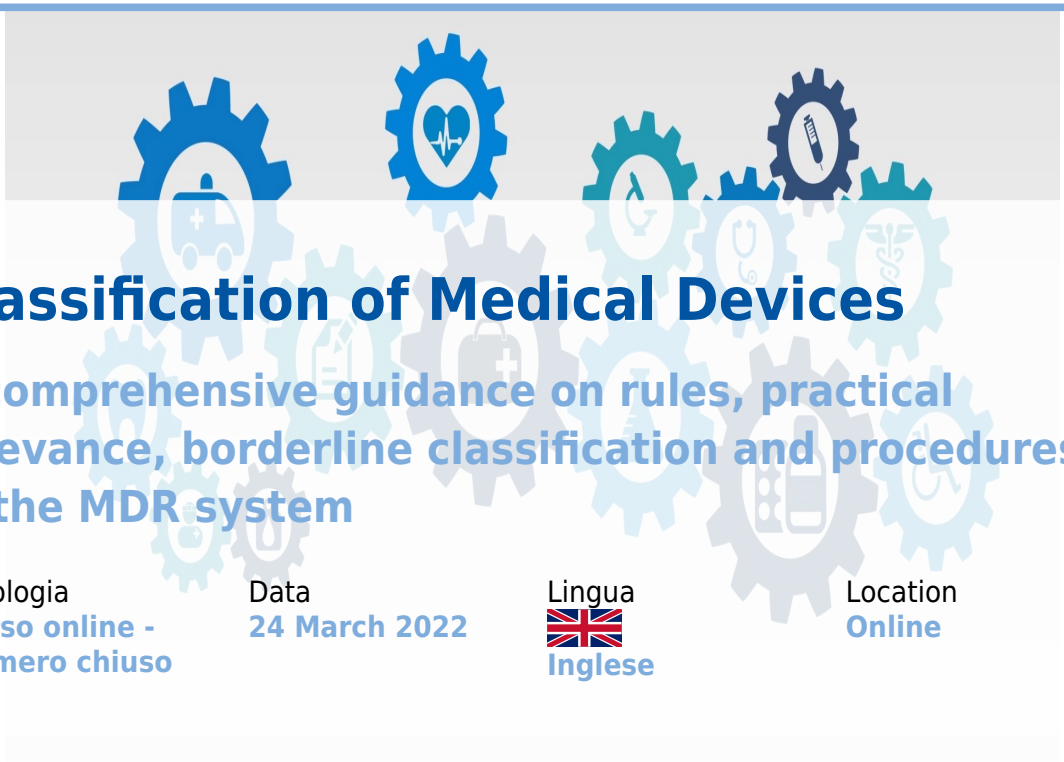
LIFE SCIENCE ACADEMY



Classification of Medical Devices

A comprehensive guidance on rules, practical relevance, borderline classification and procedures in the MDR system

Tipologia	Data	Lingua	Location
Corso online - Numero chiuso	24 March 2022	Inglese	Online

INTRODUZIONE

The classification of medical devices in the EU is set out in Annex VIII of Regulation (EU) 2017/745 on medical devices (MDR) and in the recently published MDCG Guidance (MDCG 2021-24).

The classification of a product as device and specific risk class has practical relevance for the market access strategy, the research and development, the conformity assessment procedure and data prerequisites in the pre-clinical, clinical and manufacturing module of the technical dossiers as well as the labelling, post market and traceability requirements.

This course is dedicated to the detailed understanding on the legal basis and guidance of the classification logic, the medical device definition, how to carry out classification, which procedure to follow for classification requests with notified bodies or competent authorities and the practical regulatory relevance of classification on the technical documentation and the conformity assessment process.

The course will give typical examples for each classification rule and will focus on borderline products such as medical device software, substance-based devices, injectable devices and device-drug combinations.

PROGRAMMA

The course will cover the following topics:

- Classification of medical devices in the MDR and MDCG 2021-24. Impact on conformity assessment and data requirements.
- How to conduct classification – a step by step approach. Procedure with notified bodies and Competent authorities.
- Borderline examples, critical points and latest developments.
- Combination products, substance-based devices, software.

A CHI È RIVOLTO

The course will be of interest to anyone involved in the classification process of medical devices:

- R&D Department
- Quality Assurance
- Clinical Department
- Regulatory Affairs
- CROs

Participant Experience
Both newcomers and experts

TECNICHE DIDATTICHE

Presentations and examples and Q&A.
Participants are welcome to share specific cases that can be discussed during Q&A.

DOCENTE/I

Arkan Zwick

Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria

Mr. Arkan Zwick is the Corporate Regulatory Affairs Director of CROMA Pharmaceutical, Austria. CROMA is a private global pharmaceutical and surgical company with products in ophthalmology, orthopedic and aesthetic dermatology. With more than eleven years of regulatory professional experience Arkan´s role includes regulatory advocacy for drug, medical device, combi products and cosmetic compliance projects as well as in house legal advice for contract management, merger and acquisition, and intellectual property projects. He is responsible for the company's regulatory compliance in the EU working with several notified bodies and for global market authorizations in the Americas and Asia-Pacific. Arkan has a master's degree in Law from the University of Vienna and a PhD in European Law. His expertise includes in house legal and regulatory consulting as well as lecturing at the University of Applied Sciences in Vienna and scientific board member and speaker on life cycle conferences and trainings. He is fluent in English, German and French.

COSA SAPRAI FARE DOPO IL CORSO

- Understand how to classify your medical device
- Understand the criticality of intended use and medical purpose wording
- Anticipate the impact of classification on your technical dossier and conformity assessment process
- Understand the latest developments in EU MDR

DURATA E INFORMAZIONI UTILI

This online training consists of 1 module:

24 March 2022 from 9:00 am to 1:30 pm CEST

Some days before the online training you will receive all details about the connection.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

QUOTE ISCRIZIONE

Early Bird: **€ 465,00*** (until 24 February 2022)

Ordinary: **€ 595,00***

Freelance – Academy – Public Administration**: **€ 370,00***

* for Italian companies: +22% VAT

** *Early Bird discount not applicable to Freelance – Academy – Public Administration fee*

The fee includes: tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

SEDE DEL CORSO

Online interactive training on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before the training.