IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Classification of Software as a Medical Device (SaMD) and Medical Device Software (MDSW)

12 November 2025

Master the complexities of software classification under the Medical Device Regulations (MDR), ensuring compliance and clarity with expert insights into Medical Device Coordinators Group (MDCG) guidelines. Regulatory frameworks will be discussed and practical case studies will be included (to aid the learning process).

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Course overview

Navigate the complexities of software classification under the Medical Device Regulation, to ensure compliance and avoid regulatory pitfalls. Attend this course to gain expert insights, so that you can confidently apply the MDCG guidelines and enhance your approach to medical device software classification.

Join us for an insightful course delving into the complexities of software classification under the Medical Device Regulations. With the flawed Classification Rule 11 you need expert advice to navigate this opaque topic effectively. This course, led by a key participant in the drafting process of the Medical Device Coordinators Group (MDCG) guidance, provides invaluable context to help you read between the lines and understand the true intent behind its wording. Don't let the convoluted language and cautious interpretations by regulators trip you up.

The course includes comprehensive case studies to solidify your understanding, allowing you to apply what you've learned to real-world scenarios. From our expert course leader's insider perspective, you will get a clear interpretation of the MDCG guidelines, ensuring you are well-prepared to navigate and apply them in your work.

We will also explore the Helsinki Procedure, a crucial framework for resolving disputes and providing guidance on challenging classification issues.

Benefits of attending

By attending this course, you will:

- **Examine** the implementation and classification rules
- **Understand** what is behind the convuluted MDCG language
- **Master** the key concepts to classify medical device software
- **Learn** how to apply the classification rules to real-world examples
- **Explore** your options when faced with a disagreeing notified body or unfair competition

Who should attend?

Any professionals that are integral in navigating and applying the complex classification rules for software as a medical device (SaMD) or medical device software (MDSW) under the current regulations, including:

- Regulatory affairs specialists
- Legal professionals in the medical device industry

Programme

Classification of Medical Device Software

- Implementing rules
- Classification rules
- Software that drives or influences the use of a (hardware) medical device
- Classification rule 11
- International Medical Device Regulators Forum (IMDRF) SaMD risk type determination
- International Medical Device Regulators Forum (IMDRF) SaMD risk stratification framework and its pitfalls
- Classification rules 13, 15, and 22

Case studies - Classification

Borderline cases

- Borderline manual on qualification and classification
- Helsinki procedure
- Dispute resolution and fair competition

Presenter

Koen Cobbaert

Koen Cobbaert works for Philips as a quality, regulatory, and standards expert. Through trade associations COCIR and DITTA, he represents the industry at the European Commission and the IMDRF on matters related to software and artificial intelligence. He also contributes to various standardisation organizations focusing on software and artificial intelligence.

In the legislative domain, Koen chairs COCIR's and DITTA's software focus groups, representing its members at respectively the European Commission MDCG workgroups on Borderline and Classification and New Technologies and at the international level at the International Medical Device Regulators Forum (IMDRF) workgroup on artificial intelligence. Koen is also an advisor in the SaMD workgroup at the Global Harmonization Working Party (GHWP). Currently, Koen is engaged in various proposed EU legislation relating to artificial intelligence and data (AI Act, Machinery Regulation, General Product Safety Directive, Data Act, European Health Data Space…). Aside from various publications through trade associations, Koen also edited the book Software as a Medical Device, published through the Regulatory Affairs Professionals Society (RAPS).

In the standardization domain, Koen is a member of CEN-CENELEC's Industry Advisory Forum, and he is delegated as a Belgian expert to IEC JTC 1 SC 42 on artificial intelligence, CEN-CENELEC JTC21 on artificial intelligence, ISO TC215 JWG7 on health informatics, and to the IEC SC62A Advisory group on Software, Networks, and Artificial Intelligence (SNAIG).

Koen has a Master of Science in electrical engineering and safety risk management. He has over 15 years of hands-on experience establishing regulatory and market-access strategies for medical device software, performing worldwide regulatory submissions, and moderating risk management and clinical evaluation for software applications for general radiology, oncology, neurology, cardiology, orthopaedics, and clinical pathology. He has worked on software applications for pattern recognition, computer-aided detection, reasoning engines, clinical pathways, and other clinical decision support systems, including mobile apps, embedded software, and software operating in the cloud.

Course date

12 November 2025

Live online
09:00-12:30 **UK (London)** (UTC+00)
Course code 15441

GBP **350** ~~400~~
EUR **490** ~~560~~
USD **562** ~~640~~
Until 08 Oct

How to book

Online:
ipi.academy/3094

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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