



# CM100V Medical Technology Development under the Med- ical Device Regulation 4.0 cred- its

Medicinteknisk utveckling enligt MDR

This is a translation of the Swedish, legally binding, course syllabus.

If the course is discontinued, students may request to be examined during the following two academic years

## Establishment

Course syllabus for CM100V valid from Autumn 2022

## Grading scale

P, F

## Education cycle

First cycle

## Main field of study

Medical Engineering

## Specific prerequisites

Bachelor's degree in engineering or biomedical science. English B

## Language of instruction

The language of instruction is specified in the course offering information in the course catalogue.

## Intended learning outcomes

After completion, the participant will be able to:

- Apply the current medical technology regulations to medical technical product development
- Identify critical risks in the development of medical technology products
- sketch clinical trials including medical devices
- Identify needs for quality management systems applied to the development of medical technical products

## Course contents

The course includes a review of the following contents:

- applicable directives, laws and regulations, including MDR
- liability issues
- applicable standards
- requirements for CE marking of medical devices
- requirements for clinical trials of medical devices
- the concept of quality
- requirements for a quality system
- risk management
- product and after-market monitoring

## Examination

- TEN1 - Written exam, 4.0 credits, grading scale: P, F

Based on recommendation from KTH's coordinator for disabilities, the examiner will decide how to adapt an examination for students with documented disability.

The examiner may apply another examination format when re-examining individual students.

## Ethical approach

- All members of a group are responsible for the group's work.

- In any assessment, every student shall honestly disclose any help received and sources used.
- In an oral assessment, every student shall be able to present and answer questions about the entire assignment and solution.