Vak: Engineering rules for medical devices — credits: 5

Vakcode	ELVH18GERMD
Naam	Engineering rules for medical devices
Studiejaar	2024-2025
ECTS credits	5
Taal	Engels
Coördinator	J. Zijlstra
Werkvormen	Onderwijs
Toetsen	Engineering rules for medical devices - Opdracht

Leeruitkomsten

The course deals with (not necessarily technical) aspects which are of specific importance for engineering and bringing to the market of medical products. It consists of 3 parts: Medical Ethics, Ergonomics of Human Factors and Medical Device Regulation.

Medical Ethics

The student can:
- recognize the different ethical theories and apply them to an arbitrary case;
- deal with the ethical aspects associated with the professional and research practice;
- compose an information and informed consent form in accordance with the regulations of the medical ethical committee;
- analyze a medical-ethical or research-ethical problem, using a six-step process;
- present a well-argued viewpoint on a medical-ethical or research-ethical case.

Ergonomics of Human Factors

The student can:
- on a basic level identify, explain, and evaluate the impact of various personal attributes (physical, sensory, and cognitive HF aspects);
- analyse the effect of physical environment factors on comfort and performance;
- apply addressed human factors principles in design.

Medical Device Regulation MDR

The student can:
- understands the regulatory environment for the development of a medical device.
- knows impact of MDR and CE for product design and use;
- knows the route to obtain product conformity and approval by notified body;
- knows the different risk classes of medical products;
- be familiar with Safety Requirements and Technical Construction File;
- can apply the Medical Device Regulation in medical product design.

Inhoud

Medical Ethics

The Ethics course gives an introduction to the theory of medical and research-ethics. The student takes note of a number of classical ethical approaches and can argue them on a medical-ethical and research-ethical case.

Ergonomics of Human Factors
- An introduction to the scope of Human Factors (HF) and ergonomics.
- Sensory HF: Physical environmental factors, heat, light and vibration and their measurement.
- Physical HF: Anthropometrics as related to product and environment use.
- Task analysis including all HF aspects, as tool for research and design.
- Anatomy and biomechanics in relation to Human Factors.

Medical Device Regulation MDR

Create awareness of dedicated legislation, concerning safety and quality, when designing and using medical devices.

Opgenomen in opleiding(en)

Exchange Biomedical Engineering (autumn)
Minor Biomedical Engineering

School(s)

Instituut voor Engineering

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