Q1. (5p)
1.1 Explain briefly the concepts sensitivity and specificity of a clinical test. How they can determined? (2p)
1.2 Explain three things, which affect on the regulatory process for a medical Device. (3p)

Q2. (5p)
2.1 Explain the different cytotoxicity tests that are made for materials/devices intended to be implanted to the body. (3 p)
2.2 Compare the different cytotoxicity tests (2 p)

Q3. (5p)
3.1 Explain, why in vitro and in vivo tests are done, what kind of information they will provide. (5p)

Q4. (5p)
4.1 Why modeling of physiological systems differ from modelling of engineered objects, for example model of the heart versus model of a car engine? (5p)

Q 5. (5p)
Define shortly (answer to separate answer paper)
Correct answer + 1p
Almost correct answer + 0.5p
Empty answer 0p

a. Aseptic working
b. Biocompatibility
c. Biological indicator
d. CE-marking
e. Disinfection
f. Histology
g. Implantable device
h. Notified Body
i. Standard
j. Toxicity