



EXAM 14th of December 2009
BME-1176 Biomedical Engineering C

Q1. (5p)

- 1.1 Explain briefly the concepts sensitivity and specificity of a clinical test. How they can be 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

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