3. In the ethical point of view, which are the requirements for clinical studies (studies done on humans)? (3p)

4. In European Union, medical devices are be classified into the groups I, IIa, IIb and III. According to which factors is this classification made? (4p)

5. You want to sterilize a product containing Geopacillus stearothermophilus using an autoclave (121°C). The microorganism has a D121-value of 1.5 min, at 121°C. The product has initially 100 microorganisms / unit. How long do you have to sterilize it to achieve SAL of 10^{-6}? (3p)

Exam BME-1177 Biomedical engineering: Research and Productization 18.12.2012

Examiner: Niina Ahola

NO literature or calculators allowed.
Answer in English!

1. Define shortly (1 p each)

a. Medical device
b. Bioburden
c. Hemocompatibility
d. CE Mark
e. GMP
f. Applied research
g. Notified Body
h. Biological indicator
i. Aseptic working
j. Diagnostic accuracy

2. Are the following statements true or false? Explain also shortly why. (1 p each)

a. Human person is a significant particle resource in a clean room.
b. Cytotoxicity means toxicity in genetic level.
c. Steam sterilization is a suitable method for the sterilization of bone fixation screws made of polylactide.
d. Sterilization and disinfection are synonyms.
e. Cochlear implant is an active implantable device.
f. Functional failure of medical devices is the main cause of hazards.
g. Agar diffusion test is one of the in vitro biocompatibility tests
h. Clean room clothes are always disposable.
i. Biological fluids are not allowed to be used in in vitro testing.
j. Paper is not allowed to be used as a packaging material for products that are sterilized.