Exam

ELT-61236 Biomedical engineering: Research and productization

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NO calculators or dictionaries allowed! Answer in English!

1. Define shortly (2 p each)
   a. Medical device
   b. Predicate device
   c. Diagnostic accuracy
   d. GMP
   e. D-value
   f. Bioburden
   g. Biocompatibility
   h. SAL

2. Are the following statements true or false? Explain also shortly why. (3 p each: true/false correct 1 p, explanation correct 2 p)
   a. Sterilization and disinfection are synonyms.
   b. Regulations concerning medical devices are identical worldwide.
   c. Informed consent is the main precondition for human experiments.
   d. Control of conception can be the purpose of a medical device.
   e. If you have a slight flu, it does not prevent you from working in a clean room.
   f. Clinical tests are used to evaluate toxicity of materials.
3. How are medical devices classified in Europe? Which are the factors that the classification is based on? (6 p) Which classes do the following medical devices belong to (1 p each):

   a. Antibiotic releasing and bioabsorbable polymeric bone fracture fixation screw.
   b. Heart pacemaker
   c. Plaster
   d. Urinary catheter (for temporary use)
   e. Knee prosthesis
   f. Hospital bed
   g. Contact lenses
   h. Sutures

4. 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? (6p)

5. What kinds of hazards are associated with electrical medical devices? (6p)