



EXAM 1<sup>st</sup> of February 2010

BME-1176 Biomedical Engineering C

NOTE! Write answers to questions 1.1, 1.2, and 2, each to separate papers, please!

Q1. (5p)

- 1.1 What is the difference between the concepts medical data, medical information, and medical knowledge? Describe their relationship by using an ECG as an example. (3p)
- 1.2 Explain term Good Manufacturing Practice. (2p)

Q2. (5p)

What information is needed for mathematical models for example FEM model of a blood flow in blood vessel?

Q3. (5p)

Mark correct answer, is the claim correct or wrong.

Claim	TRUE	FALSE
Regulatory affairs and marketing strategy have nothing in common		
Regulations of medical devices are equal in every country		
Regulatory processes with the authorities require always tons of documentation		
ISO 13485 is a quality system standard of medical devices		
Implantable devices are the subclass of the invasive devices		

Q4. (5p)

Explain, why *in vitro* and *in vivo* tests are done, what kind of information they will provide.

Q 5. (5p)

Explain following terms and phrases:

- |                 |                                 |
|-----------------|---------------------------------|
| A) Cleaning     | F) Bioburden                    |
| B) Disinfection | G) Clean room                   |
| C) Sterile      | H) Living particle              |
| D) Antiseptic   | I) Laminar flow (in clean room) |
| E) Aseptic      | J) Histology                    |