

- 1. Welcome Opening**
- 2. Organisational details**
- 3. Approval of the minutes of first CMC Meeting**
- 4. Presentation of the result of the second CMC-Board meeting/Development of CMC-Procedures**
 - a. Basic Principles
 - b. Standard CMC-Process
 - c. Tools for communication and co-operation including templates and formats
 - d. General principles on transparency, website, "web-minutes" of the first CMC-meeting
- 5. Logo/slogan competition**
- 6. Prepared Decisions:**
 - a. Borderlines and Classification**
Discussion and decision of drafted decision
 - b. Best Practice Guide Notified Bodies mandatory**
Discussion and decision of drafted decision
 - c. Labelling: Manufacturers address**
Discussion and decision of drafted decision
- 7. Acute Major issues**
 - a. PIP-Case**
Report and Discussion
 - b. EMKI-Case**
Report and Discussion
- 8. NWIP proposed by the CMC-Board for CMC consideration:**
 - a. Give NBOG the task to specify the criteria for designation
 - b. Design a new designation procedure for Notified Bodies
 - c. Clarify the content of Notified Body certificates
 - d. Clarify the content of declarations of conformity

- e. Improve the readability of instructions for use
- f. Agree on consistent rules in respect of “periods of grace” to be allowed to manufacturers in order to allow non-conformities to be addressed or in cases of reclassification of devices
- g. Coordination of external consultations

9. Home work list

10. AOB

11. Next meeting etc.

12. Closing