



The European Association  
Medical devices - Notified Bodies

## PRESS RELEASE

### Code of Conduct (CoC): adopted as a mandatory commitment for Team-NB members

On the October 9th, 2012, the Team-NB members met in a general assembly. They adopted the CoC version 3 by a large majority (79%). The members agreed to consider the requirements of CoC to become mandatory for all Team-NB members.

The document's purpose is to improve the implementation of the European CE marking certification of medical devices through clarified organizational criteria, management of competences and assessment practices.

The version 3 of this document contains the following topics :

1. Implementation, enforcement and monitoring of the Code of Conduct
2. Qualification and Assignment of Notified Body Assessment Personnel
3. Minimum time for Notified Body assessments
4. Unannounced visits
5. Sampling of class IIa and IIb technical files
6. Design Dossier Reviews
7. Rules for subcontracting
8. Rules for Certification Decisions

Further revisions will be made to be in line with the new developments of the European legislation.

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