



The European Association  
Medical Devices - Notified Bodies

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**Press Release**  
**Agreement on new Medical Devices legislation**

Team-NB fully supports the European Commission's plan to strengthen the European medical devices legislation for the future.

TEAM-NB agrees we need more transparency in the system, clearly prioritising as a key point the safety of patients and restoring the trust they can have in the healthcare system.

Team NB members have started to discuss the requirements identified in earlier drafts of the regulations in an attempt to harmonise interpretation and implementation prior to the documents being voted on and published.

The earlier draft regulations discussions have resulted in a common interpretation that is provisionally documented in the TEAM-NB Code of Conduct.

The Code of Conduct version 3.4. has been adopted in March 2016 and is freely available from the association's website [team-nb.org](http://team-nb.org) (link with doc). It will be the basis of the peer review audits of all members during 2016-2017.

Today Team-NB set up working groups to work on the new available politically agreed texts for the new regulations in order to help the members to identify and interpret the impact of the new requirements on the notified bodies. The aim is that the working group will come with guidelines to support the members in submitting their application in the quickest time and be ready to pass their designation audit against the new regulations.

There are a number of areas of improvement in the current European regulatory framework for medical devices: harmonization of the supervision of the work of Notified Bodies ; Product Responsible Person; access to Post Market Surveillance data, content clarification of technical file in the legislation; product inspection; unannounced visits,...

Ensuring a high level of patients' safety and confidence and promotion of innovation in the medical device industry are key concerns of Team-NB.

Our association has been very much involved in the debates which took place in the Parliament in the last years. In this context, the Team NB members agree to be submitted to a strong and harmonized assessment and surveillance system by the members' states and the Commission.

As always, Team-NB is aiming to help the notified bodies members to provide to the sector the best possible services to ensure a harmonious standard among the members. The key point remaining the safety of patients and the trust in the European healthcare system.