



The European Association of  
Medical devices Notified Bodies

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## PRESS RELEASE

### Team-NB Code of Conduct for Notified Bodies V5

At the October 2023 General Assembly of the Team-NB association, it was decided to review the Code of Conduct.

The former version of the Code of Conduct dated 2019 and had only been updated to remove any conflicts to the EU MDR and IVDR.

This Code of Conduct aims to harmonize our practices and also intends to show that Notified Bodies take their responsibilities on subjects such as harmonization, governance and transparency. We hope that the adoption and implementation of this version 5 of our Code of Conduct will allow us to work serenely in a consistent manner.

Since the end of 2023, the members of the "Code of Conduct" working group, representing 16 members, have worked hard to draft a new version of the Code of Conduct. The preliminary version was presented to all members for comments. Many comments were received showing the interest of members in this important document. All members comments were reviewed to improve the document twice.

In this version 5 of the Code of Conduct, the changes and new inputs include:

- Removal of references to Directives and general update of references and terminology
- Compliance with Medical Device Coordination Group (MDCG) Guidance, Team-NB and NBCG-Med Papers
- Estimation of time needed for Technical Documentation review included
- Clarified requirements for unannounced audit
- Detailed explanation of re-certification requirements
- Estimation of time needed for Corrective and Preventive Action (CAPA)
- Included examples for Structured Dialogue
- Enforcement changed to complaint / appeal process

Of course, the Code of Conduct will still need further improvements, and we have already received topics that our members would like to include in the near future.

The project proposal was approved thanks to our electronic vote mechanism on September 16<sup>th</sup>.

It is available on the Team-NB web site thanks to the following link: ([Team-nb Documents - Welcome to Team NB | Team NB](#))

In case of any further clarification needed, please contact [schlemmer@team-nb.org](mailto:schlemmer@team-nb.org)