



The European Association of  
Medical devices Notified Bodies

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### **PRESS RELEASE**

#### **Team-NB Code of Conduct for Notified Bodies V5-0**

The version 5 of the Code of Conduct was adopted by a large majority of members thanks to our electronic vote mechanism. Following that adoption, considering the important changes in this new version, the members confirmed their involvement by signing the newly adopted version.

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.

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.

By joining the association, members undertake to accept the Articles of Association as stated in the article 8 considering "rights and obligations of members". The adoption of the Code of Conduct shall have full effect and shall be considered definitive within the framework of the Association's regulations, having regard to the groups that are members of the Association. Any decision of a member not to sign the new version of the Code of Conduct will in fact be a decision to no longer be part of the association.

Below is the list of the members who endorse it.

Today 42 of our 44 members endorse it.

AFNOR	EUROFINS France	PCBC
BSI	Eurofins E&E Finland	QMD services
CeCert	GMED	RISE
CE Certiso Kft	HTCert	SGS Fimko
CERTIQUALITY	ICIM	SIQ
CNCps	ICR	SZUTEST
DEKRA Certification B.V.	IMQ	TÜV NORD
DEKRA Certification GmbH	INTERTEK MNB	TÜV NORD Polska
DNV	Kiwa Cermet	TÜV Rheinland
DNV MEDCERT	Kiwa Dare	TÜV Rheinland Italia
DQS	MDC	TÜV SÜD
EKAPTY	MTIC	TÜV SÜD Danmark
ENTECERMA	Neoemki	UDEM Adriatic
EUROFINS Italy	NSAI	UDEM TR

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)