The European Association
Medical Devices - Notified Bodies

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Position paper **Team NB Statement**	

Team-NB members wish to emphasize that Notified bodies work within a strict regulatory framework and put patient safety at the heart of their decision making when conducting the conformity assessment of a medical device. We would like to reassure the public that out of the hundreds of thousands of medical devices that help improve people's lives, very few are a cause for concern as reported by the International Consortium for Investigative Journalism.

Major change is also happening across the medical device industry and Team NB <http://www.team-nb.org/> members welcome the new European regulations, currently in their transition period, coming into force in May 2020 and 2022. These contain a series of extremely important improvements to modernise the current system, take into account all technological and scientific developments in the sector and enhance the safety regime for all medical devices available in the EU. The European Commission are currently investing in the capability of EUDAMED - the European medical devices database - which will help in the sharing of evidence based information, making the process more robust and transparent.