The European Association
Medical devices - Notified Bodies

RELEASE

Telegraph article concerning potentially dangerous medical implants for sale in Europe

In the article of the Telegraph dated October 22nd (*), following undercover investigation, the authors disclose that 3 Notified Bodies have practices that may raise serious questions over the safeguards of patients.

Team-NB , the European Association of Notified Bodies in the sector of medical devices, wants to bring to the attention that its members are commited to ensure the safety of Medical Devices on the European market and to contribute to public health. This commitment, which has some regulatory and ethical aspects, can be achieved by means provided by law and also by actions on a voluntary basis.

The Notified Bodies were notified through the legal framework in the regulatory Conformity Assessment and Certification of Medical Devices. The work of Notified Bodies is a key corner stone of the EU legislative system to safeguard public health. The system has proven to meet its objectives in this regard but needs improvements in its implementation . Indeed, since its adoption several changes took effect such as the increased number of Member States and with that the number of Notified Bodies almost doubled since the beginning. Also new and more complex technologies have been introduced. Many items which bear an potential improvement are already addressed in Directive 2007/47/EC. Moreover new regulations have been adopted on at a draft level by the Commission on September 26th 2012 with the aim of further improvements and harmonisation among Competent Authorities and Notified Bodies.
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.

To add to this improving legal framework, some Notified Bodies decided to establish a Code of Conduct (**). This Code of Conduct was adopted on a voluntary basis. On the October general assembly, the Team-NB members adopted the Code of Conduct and agreed to consider the requirements of Code of Conduct 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.
This Code of Conduct adoption as mandatory gives a clear signal that signatory Notified Bodies declare to be fully aware of their responsibility to ensure that certification of Medical Devices complies with the Directives.

(*)Telegraph article: http://www.telegraph.co.uk/health/9626756/Faulty-medical-implants-investigation-Patients-health-put-at-risk-by-unscrupulous-EU-regulators.html

(**) Code of Conduct for Notified Bodies under Directives 90/385/EEC, 93/42/EEC and 98/79/EC "Improving implementation of the European CE certification of medical devices through harmonization of quality and competence of Notified Bodies":

http://www.team-nb.org/index.php?option=com_docman&task=cat_view&gid=17&Itemid=38&lang=en

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