



The European Association Medical Devices - Notified Bodies

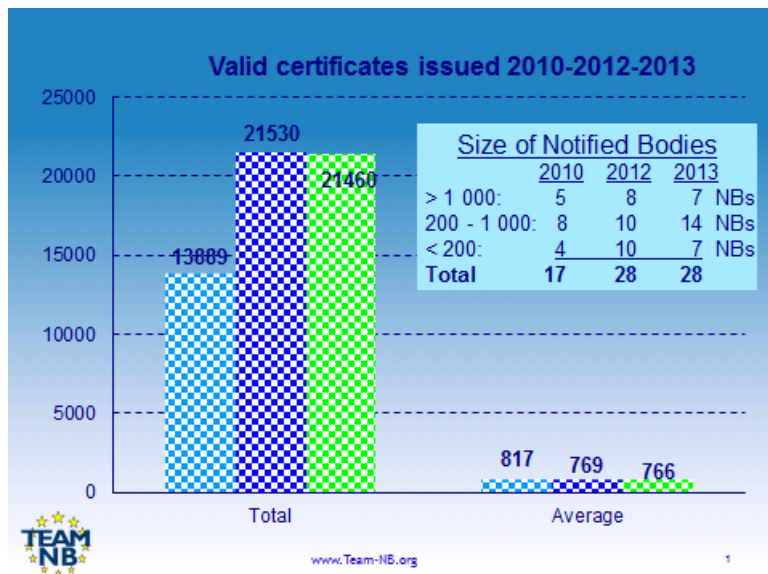
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TEAM-NB *The European Association for Medical Devices of Notified Bodies* is a non-profit association, whose members are active in the field of certification of medical devices. The association is proud of valuing and promoting high technical and ethical standards as defined in its Code of Conduct.

For the third time, TEAM-NB has run a survey among its members to analyse the certificates being issued, trying to differentiate between various directives and types of certificates. For the second time, as last year, all members provided their data. Still where relevant the data are being compared to the 2012 and 2010 analysis.



Total number of CE certificates both on total and on average remained steady between 2012 and 2013. The average had declined in comparison to 2010 probably because smaller notified bodies have provided their data in later years but not in the 2010 survey.

We may also notice globally an increase in the size of NBs with a decrease of the smaller NBs with only 25% in 2013 against 36% in 2012 and an increase of the medium size NBs with 50% in 2013 in comparison with 36% in 2012.

In several overall slides some separate data will be presented for small, medium and large Notified bodies.

Vast majority of certificates are issued under MDD, IVDD is stable and AIMDD is growing in comparison with the 2 previous surveys. When comparing the annexes it is clear that a vast majority of certificates is issued under the Full Quality System routes, 80% in AIMDD, 71% in MDD (including design examination certificates) and 58% in IVDD. For each of the directive the percentage of certificates issued under this route has increased compared to the 2010 analysis.

Number of new certificates issued after a significant drop to 3120 in 2012; increased again significantly with a growth of 62%. This appears to be related to the effect of a group of

notified bodies reissuing all certificates at the time of transition into revision of MDD/AIMD in 2010.

Total number of ISO 13485 certificates on average have declined somewhat in 2013 of an additional 10%. A substantial number of certificates were withdrawn in 2013 as in 2012, many of which are for cause. That reduction in certification could be explained to the increased level of withdrawn certificates. Overall this indicates the regulatory expectations are increasing and TEAM-NB members are toughening up.

Certification seems stable in terms of companies within EU versus outside of EU with a small increase in 2013 of 2% of EU companies.

As for staff, there seems to be a slight decrease compared to 2012. Anyway members employ a greater percentage of full time employee staff 64% than subcontractors.

Although most work still is done by own staff, the percentage of available subcontractors seems growing.

This increased numbers of contractors could be due to existing Notified Body employees deciding to leave and become contractors. This is primarily due to the auditors gaining greater financial reward by becoming contractors but wishing to remain attached to a NB so as to ensure that they obtain all the latest information concerning changes..etc to regulations through the NB and it is also a good baseline of earnings which they supplement with more lucrative consultancy work.

In case of any further clarification needed, please contact info@team-nb.org