Notified bodies dropping like flies? New-style authority audits cause near-50% cull
Today
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At least five notified bodies have been sanctioned so far under the new-style joint audits resulting from a call for tighter EU medtech regulatory controls.

Talks of these joint audits, carried out by a mixed competent authority team together with EU Commission officials, had kicked off last year after former Commissioner John Dalli called for a series of urgent measures to be implemented following the PIP breast implant debacle (www.clinica.co.uk, 10 February 2012). *Clinica* understands that the new-style audits were already well underway this year and twelve notified bodies in total have been subject to the joint audits.

According to the European Commission's Nando database of notified bodies, three notified bodies have had their certificates withdrawn under the Medical Devices Directive (MDD), one under the Active Implantable Medical Devices Directive (AIMDD) and one has had its activities suspended under the MDD.

Of the five notified bodies named so far, two are in Turkey, one in Lithuania, one in Slovakia and one in the UK. In the case of Lithuania, this was the country's only notified body.

Nor is this the full picture. While the Nando database is updated more frequently than before, and timelines have been shortened to meet transparency needs, the current database is still not fully up to date, nor entirely comprehensive.

It is likely that are more than the five named manufacturers that have been penalized.In some cases, *Clinica* has learnt, the joint audits have resulted in partial suspension, for example not allowing a notified body to take on new customers, not allowing new products to be added to certificates, or temporary restrictions in scope.

This detail, Gert Bos, president of TEAM-NB and head of regulatory and clinical affairs at BSI Medical Devices told *Clinica*, cannot be added to Nando, "so you will not likely be able to find it anywhere in the public domain".

Will the news of underperforming notified bodies being immediately punished be enough to convince political decision-makers that it is unnecessary to vote for the strictest and most controversial regulatory option on the table in the context of the proposed new Medical Device Regulation – the one where the European Medicines Agency becomes involved in the designation and oversight of the special notified bodies (SNBs) accredited to test those devices considered to be particularly high risk?

It is certainly the type of evidence that will make the medtech industry and the notified bodies more optimistic in their lobbying efforts.

Which notified bodies?

The following is a list of the five notified bodies known to be affected.The spread of notified bodies that were jointly audited under this first round was arbitrary. The joint audit team

aimed to select one notified body per country, where possible, including small, intermediate and large notified bodies, as well as old and new ones.

	Under which Directive	Country	NB No
Withdrawn			
Intertek Testing & Certification Ltd	MDD	UK	NB 0359
Sertika – Certification Centre for Electronic Equipment (end date of validity 17/7/2013)	MDD	Lithuania	NB 1609
Kalitest Belgelendirme Ve Egitim Hizmetleri Ltd STI	MDD	Turkey	NB 2179
EVPU a.s	AIMDD	Slovakia	NB 1293
Suspended			
Alberk QA Uluslararasi Teknik Kontrol ve Belgelendirme Anonim Sirketi	MDD	Turkey	NB 2138

Source: Nando database

The action means that there are still 75 notified bodies operating within the context of the MDD. Some have been notified for a very narrow product scope or type of testing, while others have a notification for a full range of operations under the MDD. They are split around Europe as follows:

Austria: 2

Belgium: 2

Czech Republic: 5

France: 1

Finland: 1

Germany: 14

Greece: 1

Hungary: 4

Ireland: 1

Italy: 9

Luxembourg: 1

Netherlands: 1

Norway: 2

Poland: 4

Portugal: 1

Romania: 1

Slovakia: 4

Slovenia: 1

Spain: 1

Sweden: 2

Turkey: 4

UK: 5

Under a Mutual Recognition Agreement with the EU

Australia: 1

Switzerland: 5

What does this mean for manufacturers?

Where a notified body designation is suspended, the certificates issued to companies remain valid but cannot be changed or renewed during the suspension – although in some cases suspension allows for renewal but not for additions or new certificates.

Where a notified body designation is withdrawn, this is the most draconian of actions as it means that all certificates issues by that notified body for products impacted by the withdrawal, are invalid. In other words, the basis on which the manufacturers have CE marked their products has been removed and the CE marking becomes invalid.

For companies, this means their products certified by that particular notified body can only be sold up to the batches released to market when the certificate was still valid. After that, they cannot market the products impacted by the withdrawal.

Clinica understand that there may be special transition arrangements identified in special cases, for example, where there are no alternative products. Also, authorities are supporting a fast but thorough transfer to another notified body for companies that are impacted.

May in-depth critical assessments be enough?

The ‘joint audits’ performed this year in a voluntary phase indicate this new system delivers very serious in-depth critical assessments, Dr Bos told *Clinica*. So far, he said, it has resulted in at least two removals of designation, two suspensions, and two voluntary notified body

withdrawals, in addition to reductions in scope, and it triggered essential improvement processes in notified bodies. “TEAM-NB supports this strong increase in supervision as we see that it greatly enhances the performance of notified bodies and the willingness to participate in harmonization efforts,” he added.

Dr Bos is also optimistic that this evidence of the competent authorities, under the wing of the commission, being able to increase their level of control in a concerted manner, will “obviate the need for further control, as suggested by the ENVI report and which suggests additional input from EMA into the designation process of so called ‘special’ notified bodies”.

He concluded that the more detailed qualification requirements for notified body staff in auditors, technical file and design dossier reviewers as well as certification decision takers, would remain useful additions to the commission proposal. “But the special designation process,” he said, might well be an outdated concept now that the authorities have shown the powers they can exert on the system by strictly controlling notified bodies.”