

OLYMPUS

Your Vision, Our Future

The IVDD A view from Industry



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Olympus Diagnostica

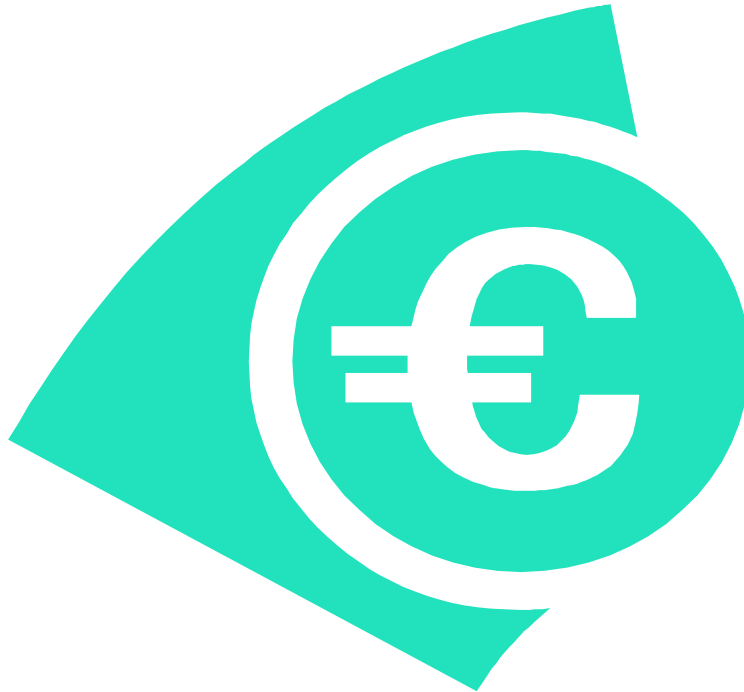
- Global company with major manufacturing facilities in Ireland, Germany and Japan
- ISO13485 Certified - NSAI
- ISO14001 Certified - NSAI
- Subject to FDA's 21CFR 820 regulations
- All devices currently manufactured are non Annex II and thus are “self declared”

The Dates

- 7th December 2003 – The end for manufacturers
- December 2005 – The end for users
- Transition period means both CE and non CE are probably still in circulation



Major Impacts to Industry (1)



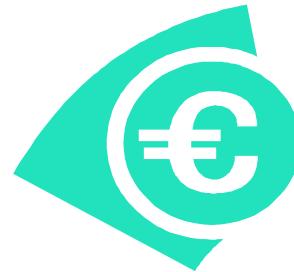
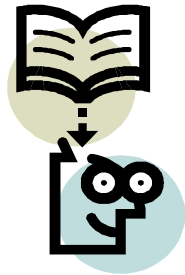
Cost factors

- New leaflets/user guides.
- Added languages – translation of leaflets, user guides and software (?)
- New EU countries admitted - many want their own language – Lithuania!
- Bigger leaflets mean bigger boxes.
- Stock obsolescence.

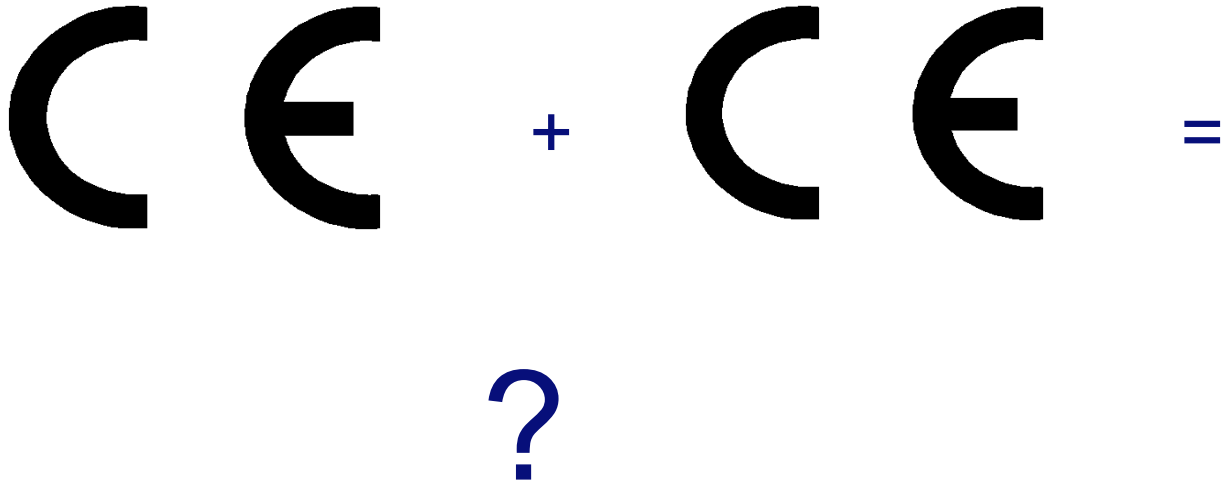
Cost factors

- Annex II manufacturers have to have additional notified body involvement and additional audits
- Traceability requirements incurred additional material and time needs
- On the positive side there is a reduction in national registrations - no more French registrations etc. And most non-EU countries (e.g. Turkey) are happy to accept just a copy of the IVDD Declaration of Conformity .

Major Impacts to Industry (2)



Combination claims



What about modification of IVDs bought from a Third Party?

- In our view, **the regulatory requirements apply whenever a device has been modified to such an extent that it can be considered as a new device**. If it is appropriate to treat the modified device as a new device, then the modifier is in the same position as if he had manufactured a device from scratch for the purposes of the regulatory requirements - i.e. if he is placing the device on the market, or falls within article 9.13, he will need to follow the appropriate regulatory procedure. Health institutions will get the benefit of the exemption in the normal way. **There are no hard and fast rules about when a modified device should be treated as a new device and every situation will need to be looked at individually**. The question is whether the device has been subject to important changes which modify its original performance. MHRA can give advice in individual cases.

14. Similarly, MHRA considers that where a person or body uses a device bought from a third party, in the context of his professional activity, in a way which makes important changes to its original purpose, that person will need to comply with article 9.13 unless the health institution exemption applies.

Impacts

- Supply of Olympus products to non-Olympus users?
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- Manufacturers should include adequate data in their technical file to demonstrate that the combination is safe and proper and does not impair the performance of the devices - or conversely that the restricted combination is known to impair performance.

Major Impacts to Industry (3)

REPORTING/VIGILANCE

Complexities

- As expected interpretation of the directive has lead to differences in understanding it
- Reporting of vigilance issues to the competent authorities is burdensome
- Olympus has a specific convolution!

Conclusions

- So far - so good
- Expect more languages
- Expect more clarification/streamlining
- We appreciate the support we get from the IMB and other CA's