

# TRANSITIONING TO THE NEW MDD – WHAT TO EXPECT FROM THE NOTIFIED BODY

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The revised MDD comes into full effect on March 21, 2010. Note that although there is no transition period per se, this date applies to any individual product that has a CE mark applied on or after March 21, 2010. Therefore, even though previously approved by a Notified Body, product lines that continue to be manufactured after March 20, 2010 must meet the new directive.

Manufacturers currently selling devices into the EU must be aware of actions their NB may take when reviewing existing products for conformity to the new directive, when submitting new devices for approval, or submitting changes to devices.

Prior to March 21, 2010, Notified Bodies were only able to complete voluntary evaluations to 2007/47/EC and all certificates issued prior to that date should reference 93/42/EC. If the requirements in the new Directive results in a change of classification for the device, then the Notified Body will have to issue a new certificate (pending assessment) to the new directive; however, if there is no change in classification, the manufacturer can continue to use the existing certificate and their declaration of conformity may reference 2007/47/EC. The notified body will then assess the products' conformity with the new directive at the next surveillance opportunity.

Some of the major changes the Notified Body will assess:

- Products that are also PPE must also comply with PPE Directive. Some PPE products also require a Notified Body. If so, a single CE mark but with two NB numbers should be used.
- Medical Devices Machinery Safety Directive 2006/42/EC – Medical devices that fulfill the definition of a machine from MSD, must meet the Essential Requirements of that directive. Note this is not the same as the PPE Directive. It is not an evaluation to the Machinery Safety Directive, only that the Essential Requirements from that directive are added to the Essential Requirements of the Medical Devices Directive
- Reclassification changes to existing medical devices that involve the central circulatory system, central nervous system, disinfecting devices, and active devices for recording x-rays.

The new directive also brings changes to the Essential Requirements that may impact Notified Body review of existing certifications:

- ER 1 - extended to include usability and ergonomics in safety of a medical device
- ER 6a – Clinical Evaluation - Was similar to previous ER14, but more later
- ER 7.5 – Phthalates – Must declare if product contains phthalates, and specific justification for products that could be used on pregnant, nursing women or infants
- ER 12 – Specific requirements for software validation to be ‘state of the art’

And one of the major changes is the change in requirements for clinical evaluation. The previous MDD only required clinical evaluation on class 2b and class 3 devices. Now, all products require at least a clinical literature study using MEDDEV 2.7. This is required for all class 2b and 3 devices, with very, very few exemptions. One of these exemptions is where the product’s performance as attested through validation or performance standards is the same as clinical effectiveness.

Ultimately, it is up to the individual Notified Body, under the watch of the CB to determine what changes will be formally assessed under the new Directive. It is always prudent for manufacturers to review their approved products with their Notified Body prior to declaring conformity with any of the European Directives.