



Medical device directive 93/42/EEC and the revision 2007/47/EC

The changes (Amendment 2007/47/EC) to the current EC Medical Device Directive 93/42/EEC become mandatory on March 21, 2010. By March 21, 2010 **all your distributed products must comply with the amended version of the Medical Device Directive.** The Amendment also updates the Active Implantable Medical Device Directive and so the same date applies for that as well.

There is no grandfathering of products that will be distributed into Europe after March 20, 2010.

Your installed base is not affected.

Here is a partial list of items of the changes to consider to help you comply with the revision to the Medical Device Directive (MDD).

Develop a plan for your company to transition to the amended MDD. You may need to make a hard decision to discontinue distribution of older or lower volume products rather than spend the time and resources to update the applicable technical files and design dossiers.

Review Annex IX (Classification) definitions and rules, as there are modifications in this Annex, which can impact the classification of your product and the conformity assessment route. Some of the changes include:

- Standalone software is considered to be an active medical device. Software validation will also be an Essential Requirement in Annex I.
- Central circulatory system definition has been corrected to include all parts of the aorta. Now includes the vessels aortic arch (arcus aortae) and descending aorta (aorta descendens) to the aortic bifurcation (bifurcatio aortae). Any devices that come in contact with these vessels will now be considered Class III.
- If device intended used is for disinfecting invasive device now Class IIb.
- Definition of "continuous use" - This now includes situations in which a device, upon discontinuation or removal, is replaced immediately by the same or with an identical device.

Check if the conformity assessment route is still appropriate. If not your current notified body certificates need to be updated. Class I Sterile and Measuring devices now have more flexibility to select a route to compliance, as they will be given the option to select a full quality assurance conformity assessment module. See Annex II of the MDD.

Whoever puts into circulation a medical device must be able to demonstrate that the product meets the essential requirements and meets the touted efficiency and performance.

Borderline products - Whether a product is a drug or device will be determined by the Primary Mode of Action rather than by the Intended Use! If you manufacture a product

which could be classified as a drug or device, be sure to read the official EU Guidance document MEDDEV 2.1/3 Rev 2 from July 2001.

Human tissue - Devices covered incorporate human tissue, blood or plasma will fall within the scope of Directive 2001/83/EC and be considered Class III. Many changes are included in this section, and companies which have these products should review the final draft proposal carefully.

Your Technical Files and Design Dossiers will need to be updated to show compliance to the updated requirements of the directive. Some of the changed requirements of the Directive include:

- Clinical data (Annex X) is required **for all products** (independent of classification, including Class I devices) and from every manufacturer. Also this imposes more stringent requirements as to what constitutes "clinical evidence" and mandates stronger enforcement by authorities. Annex X on Clinical Evaluations has been significantly amended. Be sure to read the official EU Guidance document MEDDEV 2.7.1 from April 2003 and the GHTF document SG5/N2R8 (www.ghtf.org/sg5/sg5-final.html).
- The evidence which performance related requirements are met - generally must be made on the basis of clinical data. Available for every medical device must include a clinical evaluation. **Exceptions must be justified.**
- Per Article 3 of the MDD the Machinery Directive 2006/42/EC requirements need to be considered but you don't need to CE mark to the Machinery Directive. For active medical devices you can use the expanded mechanical requirements of EN 60601-1, 3rd edition to help you show compliance to the applicable Machinery Directive requirements.
- There are many changes to the essential requirements (Annex I). Below is a small portion of the changes.

Reduce the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used shall be. There are two harmonized Usability standards that you may want to reference for this task. They are EN 62366 or EN 60601-1-6.

Phthalates are discouraged and if products do contain Phthalates they must be labelled.

Software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. Reference a harmonized standard such as EN 62304.

Ergonomics ("human factors") - Both in terms of the Essential Requirements (Annex I) and in terms of labeling, the user is now considered a key factor.

- Record retention for implanted devices has been extended **to 15 years.**
- The amendment of the MDD means each country will have to / or has transposed the MDD into its' national law. Therefore, there may be additional changes, per country, that was enacted that would apply to your product lines. Many countries are now requiring registration of all class IIa, IIb and III devices. The national registration processes can require the manufacturer to provide a copy of the device labelling. The manufacturer should provide the labelling in the native language in line with the transposed national law.

Post market surveillance Custom devices will now require a post-market surveillance system which is reportable to Competent Authorities.

European databank - Data related to Medical Device and clinical investigations will now be collected for the European databank and shared among Competent Authorities. The databank will also include information on registration, Authorized Representative, certificates and vigilance data as the product classification. The data must be submitted in a standardized format, from the notified body or for the manufacturer.

Outsourced design and manufacturing - if the design or manufacturing of a device is done by a third party, you must demonstrate that you have adequate controls in place to ensure the continued efficient operation of the party's quality system. This can, of course, be achieved through audits, receiving inspections or other means.

Notified Bodies - these will be required to perform an inspection of design documentation for a representative sample of devices using industry standard statistical techniques and "commensurate" with the risk of the device.

Notified Bodies - These will be required to perform an additional inspection of the documentation about the clinical data and literature research.



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