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Understanding Standards Harmonized to the MDD

Understanding the role of harmonized standards can be difficult for US device manufacturers because the paradigm does not match the US system administered by the FDA. In the US, a class II device requires the FDA to grant pre-market clearance. Once FDA issues the clearance letter, the device manufacturer has completed this part of the requirements. The clearance letter provides FDA concurrence in three important attributes of the device: it is safe, effective, and substantially equivalent to a legally marketed device.

In the EU, the Medical Device Directive (MDD) imposes a different set of requirements. Every device must satisfy the Essential Requirements found in Annex I. In general, the Essential Requirements focus on safety, with little (or no) requirements for effectiveness. In addition, the Essential Requirements don't involve a predicate device. The manufacturer evaluates each device on its own merits, not relative to another device already on the market.

The principal role of the Harmonized Standards is to provide a uniform way to evaluate compliance to the Essential Requirements. Article 5 of the MDD provides the important link, "Member States shall presume compliance with the essential requirements [for] devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the Official Journal of the European Communities"

The idea here is that a manufacturer can demonstrate conformance with the Essential Requirements by using the relevant harmonized standard. The key is that the harmonized standards provide the pathway to demonstrate conformity. If you use a harmonized standard, then all member states should accept it. If you use a different method, then a member state can question that you meet the Essential Requirements.

How does one know which standards the EU harmonized? The easiest way is to check the list at http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm

This is an "unofficial list" since it is not the Official Journal. Near the top of the page you can find the reference to the official list.

The most important column is the second one (Reference and title of the harmonized standard

(and reference document)), which identifies the standard. The next most important is the fifth column (Date of cessation of presumption of conformity of superseded standard) which tells you when the prior standard is no longer valid. This column, in essence, defines the transition period.

As an example, consider the need to provide information to the user. Annex I, Section 13 contains the requirements the manufacturer must follow. The harmonized standard EN 1041:2008 *Information supplied by the manufacturer of medical devices* provides a way to satisfy the essential requirement. Looking in column 5 we learn that this version came into full effect on August 31, 2011. If you based conformance on EN 1041:1998, then you need to update your technical documentation.

Notice that the standard is an "EN" standard. It will contain information that relates the clauses of the standard to the sections of the Essential Requirements. This cross reference is the key that links these two pieces.

As you develop your device, you will create the necessary documentation that demonstrates conformance to the Essential Requirements. Depending on some other issues in the MDD, this documentation will be a Technical file or a Design Dossier. The documentation will list each element of the Essential Requirements and your determination of applicability. If the requirement is applicable, then you must demonstrate how you satisfy it. By far, the easiest way is to use a Harmonized Standard.

In summary, the Harmonized Standards provide the accepted path to demonstrate conformity with the Essential Requirements. You may use other methods, but you should have a solid reason. Most devices involve a Notified Body who will question you carefully before agreeing to an approach that doesn't use a Harmonized Standard.