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Revising Directive's Time-of-Use Clause May Cause Reclassification of Devices

Medical device manufacturers are required to comply with Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC by 21 March 2010. Despite having made every effort to meet the essential requirements, companies may be surprised to learn that the classification of some of their devices may be challenged. Specifically, Annex IX of the directive places a special emphasis on a new definition of a device's time of use. The implications of this shift for manufacturers were discussed during a recent meeting with French competent authority Afssaps.

The definition of "time of use" in Annex IX is as follows:

> In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means an uninterrupted actual use of the device for the intended purpose. However, when usage of a device is discontinued in order for the device to be **replaced immediately by the same or identical device, this shall be considered an extension of the continuous use of the device**.

This new definition will directly affect devices classified as Class I and Class IIa based on Rule 5 - Devices used invasively in body orifices, Rule 6 - Surgically invasive devices for transient use, and Rule 7 - Surgically invasive devices for short-term use. This means that certain devices that were considered Class I because they were for transient use (less than 60 minutes) could now be moved to Class IIa.

The biggest impact of the rule will be on products that, until now, were classified as short-term use devices. They suddenly would find themselves subject to Class IIb requirements such as invasive devices used in body orifices that are not intended to be connected to an active device (Rule 5). Tracheal tubing was one example cited during the Afssaps meeting. Currently classified as a Class IIa product based on Rule 5, tracheal tubes could be reclassified as Class IIb devices. Long term use instead of short term use would imply among other requirements to perform additional biocompatibility testings.

Regulators and industry are waiting for a revision of the MEDDEV 2.4/1 guidelines for the classification of medical devices, which has not been revised since July 2001. Examples in Part 2 of the document might help to clarify this issue. Unfortunately, there is no word on when a revision might be forthcoming.

As manufacturers grapple with compliance, competent authorities inevitably will respond that they have had more than two years to prepare for implementation of the revising directive's amendments. We can counter, however, that the European Commission also had two years to publish its guidelines.

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