The devil is in the details

Before the 4th amendment of the German Medical Device Act came into effect, there were quite some goings on at the relevant instances and offices for medical devices. The flurry of high powered activity focused not only on compliance assessment for new devices, but also on existing devices whose risk categories were being upgraded. Extremely close attention is needed when reading the classification rules – one additional half-sentence can have major implications for individual medical device manufacturers.

When the risk category of a medical device is upgraded, a higher-level compliance assessment procedure has to be implemented. In Category I the entire process is carried out at the manufacturer's, but from risk category IIa onwards, the designated offices enter the picture and are required to carry out random testing on each sub-category of products, and in category III a complete design dossier examination. "From November 2009 or thereabouts things started getting noticeably busier in the sector and we were receiving more and more inspection orders for reclassification of existing products," explains Dr Regina Maurer, certification office manager at mdc medical device certification GmbH.

Most existing medical devices were spared reclassification of their risk cate-

"The revision hasn't provided anclarity on software"

meditec INTERNATIONAL talked to Andreas Kassner, managing director of Verband der Hersteller von IT-Lösungen für das Gesundheitswesen (VHitG) e. V.

The rules in Appendix IX to the Directive on Medical Products seem rather unclear in terms of ascertaining what type of independent software should be assigned to which risk category. Is that impression correct?
Absolutely. The revision hasn't provided any clarity on software, and classification is still being carried out according to use and purpose. As software is now coming under the spotlight as a potential medical product, all clinical software systems are currently being examined as a result of this discussion - and for no good reason as far as patient safety is concerned.

What should concise classification criteria look like?
A clear functional differentiation, backed up by comprehensible examples, would be the best solution. However, uniformly classifying software according to product segment would not be helpful.

Andreas Kassner: "Software is not comparable with pharmaceutical products or medical technology"

Why not?
Software is not comparable with pharmaceutical products or medical technology, because it is used individually and has a modular structure.
150 different systems are often at work in one hospital, all coordinated in a hospital-specific manner. Even if the same systems are also employed in a different hospital, the distinction between the systems and thereby the results of risk classification may be fundamentally different – with corresponding implications for the operator in terms of test measures after updates, etc.

From what point should independent software be classified as a medical product?
Independent software does not impact directly on the patient – the doctor, nurse or other people still make the decisions. A document management system used purely as an archiving system is no more a medical product than a patient file, which receives and returns unchanged.
However, if software is used as a decision-making tool for therapy and diagnosis and this removes the responsibility from the doctor, independent software obviously becomes a medical product. Responsibility for the product is ultimately borne by the manufacturer, who also carries out the risk assessment.

gory under the survey. However, unlucky manufacturers or those selling products in specific market segments had to upgrade the classification of a large part of their product range. This happened to Chemische Fabrik Dr. Weigert GmbH & Co. KG – two-thirds of the products marketed by this manufacturer of disinfectants and dosing systems moved up from category IIa to category IIb, including those used to disinfect medical devices used in invasive procedures. "It created a lot of work for us before the March cut-off date," says Dr. Matthias Otto, safety coordinator for medical products at Dr. Weigert. "We got off lightly to the extent that the 18 products were upgraded within category II. As a result our compliance assessment procedure did not change - it just had to be formally reissued and adjusted to meet the new requirements."

Some of the classification criteria are very specific when defined in terms of contact with specific organs, parts of the body or blood vessels. For instance, blood vessels that form part of the "central circulatory system" are now listed individually in the definitions. Simple surgical-invasive instruments, which "are used specifically in direct contact with the central nervous system", have even been re-graded from category I to III. Individually these may be relatively simple forceps, which at first sight one would not expect to have such a high classification.

However, there are also generally binding conditions, for instance regarding duration of use on the patient. Previously, use of an individual medical device was authoritative in this respect. Utilisation is now considered to be continuous and therefore uninterrupted if one device is immediately replaced by a similar one, as in the case of a urine catheter for example. "Temporary" (< 60 minutes) can therefore easily become "short-term" (< 30 days) or "short-" to "long-term" (> 30 days) – with the corresponding implications.

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Under Article 13(3) of the German Medical Device Act, from 21 March 2010 manufacturers can submit an application (for a fee) to the Federal Institute for Drugs and Medical Devices (BfArM) for decision on the classification of individual medical devices or on the distinction between medical devices and other devices.

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