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THE REGULATION OF SOFTWARE FOR MEDICAL DEVICES IN EUROPE

***By Dr Mathias Klümper
and Erik Vollebregt***



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THE REGULATION OF SOFTWARE FOR MEDICAL DEVICES IN EUROPE

Introduction

At the time that the European Directives on medical devices^{1,2} were drafted for the first time in the early 1990s, software either did not play an important role as a component of medical devices in general or played only a tangential role because it was considered to be an integral part of the device. Since those early days of European medical device law, the technical environment has changed fundamentally, particularly in terms of the evolution of computer technology and the recent advances in the field of software engineering. The pure mechanical or electrical components no longer define the functions and features of medical devices as they did in the early 1990s. As a result, software has begun to play an increasingly important role with respect to the improvement of today's medical devices.

More and more devices run embedded software that is regularly updated as part of the servicing processing and, in addition, stand-alone software has started serving a more important function in controlling medical devices, including active implantable medical devices.

Although the European legislator was aware of the existence and use of software in combination with medical devices³ when drafting the Active Implantable Medical Device Directive (AIMD Directive)¹ and the Medical Device Directive (MDD)², amendments became necessary in order to take the technological advances since the early 1990s into account. Safety of medical devices that run software is becoming an important issue due to its potential dangers as more and more of the functioning of devices is controlled by the software. Software controlling for example radio therapeutic devices or surgery robots can cause great damage if it does not perform as expected. Since software decides what a device does, or offers the user options based on its appreciation of data, it differs fundamentally in role and risk management requirements from the hardware components

of medical devices. One could say that the most important differences with traditional mechanical devices are the fact that:

- virtually all of the functioning and processing of the software is not visible to the user;
- software tends or is intended to supplement user responsibility; *and*
- risks are often not obvious to the user, resulting in incidents that the user cannot expect.

For this reason, the European legislator considered in the preamble of Directive 2007/47/EC⁴ that:

'It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device'⁵.

Thus, the legislator has strengthened the role of software used for medical purposes. Consequently, Directive 2007/47/EC has also increased the requirements for software:

'Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement'⁶.

The purpose of this article is to provide an overview of the relevant amendments to the AIMD Directive and the MDD with regard to software and to draw conclusions from the amendments. In addition, the authors will outline practical information with respect to the applicable standards and the important questions of the medical device industry, including how to comply with the new rules.

Software In, and Software As, a Medical Device

Although the requirements under the amended medical device Directives with respect to software have become stricter, not all types of software are covered by the rules of the Directives.

Software Covered by the Directives

The relevant rules of the amended Directives are applicable for medical devices and accessories as defined in Articles 1, paragraph 2, point (a) of the AIMD Directive and the MDD. These provisions define a medical device as:

'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, [together with any accessories,] including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings'.

Note: text in [] only appears in the AIMD Directive.

Consequently, only stand-alone software or software that is used in combination with a medical device for the purposes set forth in the Directives is covered by the AIMD Directive and the MDD. Moreover, only this type of software has to fulfil the strict requirements set forth in these Directives, in particular the Essential Requirements.

An examination of the following three categories of software is instructive in practice for the purposes of determining which type of software is covered by the Directives:

- software itself is a medical device (stand-alone software) or is an accessory to a medical device; *or*
- software is a component or an integral part of a medical device; *or*
- all other software that is not covered by the Directives.

Stand-Alone Software and Accessory Software

Software falls within the scope of the definitions of the amended MDD and the AIMD Directive for

a 'medical device' if one or more of the following criteria are met.

First, software is a medical device in itself if the intended purpose of the software is to satisfy one of the purposes explicitly mentioned⁷ in the MDD, AIMD Directive or *In Vitro* Diagnostic Directive (IVD Directive). Software will satisfy one of these expressly defined purposes if, for example, the software is used for the proper functioning and control of an AIMD. This would typically concern the software used by devices such as programmers for pacemakers or software for interpretation of diagnostic images. For the practical assessment of the cases, the classification rules set forth in Annex IX to the MDD can be helpful in deciding whether stand-alone software is a medical device.

Furthermore, stand-alone software is classified as a medical device if it controls or influences the functioning of a medical device within the meaning of the MDD or the AIMD Directive³. This is the case if, for example, the software takes over the dose-planning function for a medical device.

The next group of software is possibly the oldest and the one with the most practical relevance. This group covers, for example, software used for either the processing of image data in X-ray or magnetic resonance tomography devices, or the analysis of long duration data from long-term electrocardiography.

Finally, software designed to be used for or by patients in order to diagnose or treat a physical or mental condition or disease may cover software in diagnosis test equipment.

The aforementioned types of software must be CE marked in their own right and must undergo their own respective conformity assessment.

Software as a Component or Integral Part

Apart from the aforementioned stand-alone software and software used in combination with medical devices, software is often used as a component amongst others, or as an integral part of a medical device. In these cases, the software is not a medical device itself since it neither has the intended purpose of a medical device on its own nor is it related to the core functions of a medical device.

These types of software are not considered a medical device as such, but rather as an auxiliary part of a medical device. The legal effect is that such software cannot and need not be CE marked on its own. Instead, the conformity assessment of the software is part of the conformity assessment of the overall medical device. The software is comparable to all other components of the medical device. However, in practice, problems concerning how to select the conformity assessment procedures might arise.

This group covers, for example, the software that controls the power management or the cooling system of a medical device.

Software Not Covered by the Directives

Until now, this article has focused on software that is covered by the Directives and is required to either undergo its own conformity assessment or is covered by the conformity assessment of the device to which it belongs. There is also a category of software that is not covered by the Directives at all.

Software that falls into this classification includes software that does not fall within the definition of a medical device, or software that is not a component or an integral part of a medical device. Since this software is not covered by the Directives, no conformity assessment and no CE marking are necessary.

This is the case, for example, for software which is used for administrative purposes (handling of patient files and data) or for educational purposes (training of physicians on how to use a specific medical device)⁵.

Summary

The classification of the different types of software used in or with medical devices and the answers to the questions of whether a CE marking and a conformity assessment are required can be summarised as shown in Table 1.

Changes as a Result of Directive 2007/47/EC

As a consequence of the amendments to the Directives, manufacturers of medical devices have to decide whether the software used in their medical devices requires CE marking. In addition, manufacturers of software that falls within the definition of a medical device as a result of the intended purpose of the software also need to decide to have the software CE marked. For example, an expert system that interprets graphics data should be CE marked as a medical device if it is put on the market as an expert system that supports Alzheimer's diagnosis based on its interpretation of brain scans.

The rules in Table 1 above and the additional criteria mentioned in the previous section provide criteria for a first assessment of the classification of the individual software. However, they help only with a preliminary assessment since the demarcation is, in practice, difficult and requires a closer look at the circumstances of the individual case at hand.

The manufacturer of software within the scope of the Directives may select a combination of Annexes to compile the conformity assessment procedures for the software.

Table 1. Types of software and whether CE marking/conformity assessment is required

Software	Directives	CE Marking
Is a medical device itself or is an accessory to a medical device	Directly applicable to software	Own CE marking required for software
Is a component and an integral part of a medical device	Not directly applicable to software	Software must be covered by conformity assessment of the medical device
Software is neither a medical device, nor an accessory, nor a component	Not applicable	No CE marking required

For the conformity assessment:

'For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification'⁸.

The state of the art in this respect is set out in a number of standards that will be discussed below.

However, the conformity assessment procedures of software as a medical device or as an accessory have to do justice to the high level of complexity of the software that is assessed under those procedures. This means that traditional testing and assessment procedures might not be adequate to bear fully the potential risks resulting from software. In addition, software is normally not built from scratch by the manufacturer that gives it its intended purpose as a medical device. This means that the conformity assessment needs to take into account what happens at the software vendors or software developers of the manufacturer⁹.

Software Standards and Guidance on Standards

As with all technology products, standards with respect to software help to ensure compatibility, interchangeability and even basic safety. Standards help to provide a framework that captures best practices and 'tested and true' solutions to recurring problems. More generally, all European New Approach Directives centre around the same principle of a body of rules with an Annex containing Essential Requirements and CE certification procedures, with a reference to (inter)national standards¹⁰. Notified Bodies and national authorities must also use these standards as yardsticks for their assessments¹¹. However, they are only a yardstick and the compliance with these standards does not automatically mean that all potential liability of the manufacturer of the medical device is excluded.

As mentioned above, Annex I to the MDD provides that:

'For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification'⁸.

Taking development into account for purposes of assessing software is critical because a pure product-related evaluation of the software released cannot address all risks associated with medical software¹².

What, then, are these standards for medical software? One can draw a distinction between voluntary adherence to standards and mandatory standards. These standards, published in the *Official Journal of the European Union* with respect to the MDD, are mandatory standards in the sense that if these standards are met, compliance with the MDD must be assumed¹¹. The latest publication with the standards applicable to medical devices (and also software) can be found in the *Official Journal of 2 December 2009*¹³.

Standards that are harmonised for the European Union with respect to software in medical devices are:

- EN 60601-1: 2006, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*;
- EN 60601-1-4: 1996, *Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems; and*
- EN 60601-1-6: 2004, *Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability*.

The aforementioned EN 60601 standards are only applicable to software in hardware medical devices and not to stand-alone medical device software.

An important new standard is EN 62304: 2006, *Medical device software - Software lifecycle processes*¹³. It defines risk management-driven lifecycle requirements for medical device software, both embedded and stand-alone. It covers the development and

maintenance of software (but not validation and release) because many discovered errors are due to defects that have been introduced after the original software has been released. It is intended to represent the current best practice in medical software and is written to be used in conjunction with ISO 13485 (comprehensive management system for the design and manufacture of medical devices) and ISO 14971 (application of risk management for medical devices). Monitoring of user feedback is provided for in the requirement for issue-resolution processes, which parallels the requirements in the Directives. There is also a connection to vigilance requirements and reporting via the manufacturer's obligation to inform the user and authorities about problems in released software and the consequences of continued, unaltered use, as well as to inform them of any available upgrades of the software (including how the user can gain access to and install them).

Two other standards relevant to software and medical device law have been developed recently:

- IEC 80001-1, *Application of risk management to information technology (IT) networks incorporating medical devices - Part 1 - Roles, responsibilities and activities; and*
- IEC/TR 80002-1, *Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software.*

Guidance with respect to questions that are not answered by the European harmonised standards and other very helpful guidance is provided by the US Food and Drug Administration on its website, which contains guidance on *General Principles of Software Validation*, on *Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software*, on *Compliance on Off-the-Shelf Software Use in Medical Devices*, and on the *Content of Premarket Submissions for Software Contained in Medical Devices*¹⁴.

How to Comply?

In general, many compliance issues arise because software development at manufacturers is

treated as an activity that needs to conform to the standards applicable to software and the Annexes to the MDD. As evidenced above, there is more to compliance than just that. In the following section, the authors will address a number of typical situations that manufacturers may encounter with respect to software.

Testing Software within the Scope of the Medical Devices Directives is a Clinical Trial

This sounds very obvious but in practice many mistakes are made with this: if a manufacturer tests software that qualifies as a medical device and either has no CE mark at all or it is a new version that is not covered by the CE mark (for example because it is an update to remedy a flaw that caused an incident), running the software for real life tests outside a clinical trial setting is prohibited.

Changes to Software

Manufacturers often make changes to software. The changed software is uploaded onto the medical devices during service or maintenance or even remotely via the Internet. If the software is a medical device or the software is certified as embedded in the device, such changes count as changes to the device for the purpose of compliance with the MDD. Therefore, if a manufacturer makes changes to CE marked software (e.g. releases a new version, new intended use, change of platform on which the software runs or solving of compatibility issues) he must ensure that:

- the software still complies with the Essential Requirements of the MDD;
- the changes are documented (see EN 60601-1-4);
- the changes are validated and approved;
- significant changes are reported to the Notified Body and to the authorities (if applicable, for example changes after an incident);
- the changes made do not change the risk class of the device – if so, the manufacturer must do a new conformity assessment; *and*
- the manufacturer contacts the Notified Body if the CE Certificate refers to versions of software.

Where Does the Medical Device End and the Network or Other Software Begin?

Now that medical devices become more and more networked and consist of software that interfaces with other software, it is important for the manufacturer to determine where the medical device 'ends' and, consequently, to determine the corresponding regulatory obligations. Indeed, Recital 6 of Directive 2007/47/EC provides that software is a medical device if specifically intended by the manufacturer to be used for one or more of the medical purposes articulated in the definition of a medical device. It also provides that software for general purposes, when used in a healthcare setting, is not a medical device. According to MEDDEV 2.1/1¹⁵:

'In the case of software intended for use with multipurpose informatic equipment a distinction has to be made between software providing for a proper diagnostic or therapeutic tool and software for handling general patient-related data. Only in the first case may a medical purpose be determined'.

For example, this distinction is difficult to make with diagnostic software that allows the doctor, while at the patient's bedside, to view diagnostic images that are enriched with other data from the patient's electronic records. There is no doubt that the modules of the software that generate the diagnostic images based on the scanner input are a medical device as such or embedded in the scanner. The question would be whether the module that provides the enriched bedside image is also a medical device. One could well argue that this module is intended by the manufacturer for diagnosis or monitoring. The problems arise from the last part of the definition of a medical device: 'and which does not *achieve its principal intended action in or on the human body* by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means' [emphasis added]. The question is how to interpret this last part. On the one hand, one could argue that 'principal intended action in or on the human body' means that only software that actually works in or on the human body falls within the definition of a medical device. On the other hand, one could

argue that this last part of the definition only serves to define the border between medicinal products and medical devices and accordingly is an element of fine-tuning rather than a core element of the definition of what constitutes a medical device. The authors feel that the interpretation that software must actually work in or on the body in order to qualify as a medical device does not do justice to the fact that stand-alone software with an intended medical purpose is supposed to be covered by the MDD according to MEDDEV 2.1/1 and Recital 6 of Directive 2007/47/EC. For example, with this interpretation, stand-alone software with an obvious intended purpose as a medical device (e.g. an expert system running on a separate computer for interpreting scans for Alzheimer's disease) would be excluded from the scope of the MDD. Therefore, the extra diagnostic module in this example should, in the authors' view, be covered by the MDD.

What to Require from Subcontractors and Outsourcing Parties?

Currently, few companies develop all elements of all their software in-house. Parts of the software can be bought off-the-shelf or, alternatively, can be developed or customised through outsourcing of these processes. These parts are then integrated into the software of the medical device manufacturer. Ultimately, the software, as put on the market by the medical device manufacturer, must meet all the demands outlined under the MDD. Consequently, the manufacturer must take certain precautions, each of which should be aimed at ensuring manufacturer control over the whole chain of development of the software concerned.

Firstly, the medical device manufacturer must ensure that the development process of the software fits the requirements imposed by the Annexes to the MDD and the applicable standards (e.g. EN 62304). The manufacturer should ensure he is always aware of the origin of all the elements of the software – the software should not contain any Software of Unknown Provenance (SOUP). Typical examples of SOUP are open source components.

Secondly, the manufacturer must ensure that all of the elements of the software have

been developed and will be followed up within the post-market surveillance (PMS) system according to the requirements in the Annexes to the MDD and the applicable standards. This means that it must also be mandatory for third parties to conform to these requirements and standards and report to the manufacturer all information that is relevant for his PMS obligations. In practice it does not suffice to include a blanket clause in an agreement that the developer 'must meet all applicable standards and conform to all applicable rules'. Rather, it is preferable to mention the standards explicitly in the agreement, thus obligating the developer to share responsibility for the software. Ultimately, however, it is the manufacturer that issues the declaration of conformity and faces regulatory liability for the software.

Thirdly, the manufacturer must ensure in case of third-party developers that he has access to (or preferably ownership of) the developer data that must go into the technical file for CE marking. If not, the manufacturer is stuck to the developer involuntarily because he may not be able to use the data in the technical file anymore after termination of the agreement with the developer. This may be especially problematic in the cases where the manufacturer has very long PMS obligations, such as with implantable devices.

Fourthly, the manufacturer must always be able to control and be informed about what is happening in the scope of his PMS system for a device. He must require his subcontractors to report and preferably control any design changes in the software that they develop, as design changes may necessitate notification to the Notified Body that audited the software and should be part of the technical file of the manufacturer.

Observe the Deadline for Implementation

Since 21 March 2010, all CE Certificates and technical files must be compliant with the new rules¹⁶. Since the MDD does not contain a transitional regime, all software on a medical device or constituting a medical device must conform to the revised MDD and the national implementing legislation¹⁷. This means that all revision of technical files and CE Certificates

must have been completed before that date with some minor exceptions¹⁸. Merely starting a procedure to adapt the technical file or certificate prior to 21 March 2010 is insufficient; the procedure must have been completed by that date.

What is Next?

National regulators involved in European legislative processes mention that a MEDDEV on software is in the making and that other expected new MEDDEVs in the pipeline may contain provisions on software.

Furthermore, given the increasingly important role that software plays in the functioning of medical devices, the European Union's medical devices legislation recast is likely to put more emphasis on software. By now it is abundantly clear that the recast may not be made public before the summer of 2010. In addition, it is not clear what effect the new Commission, installed in September 2009, and the accompanying move of medical devices policy from the Directorate General for Enterprise and Industry to the Directorate General for Health and Consumers may have on the draft recast that the Commission is now preparing.

As medical devices will become more networked or network-based, the rules and standards will have to account for this development. Some medical devices solely comprised of stand-alone software may be provided for under a 'software as a service' (SAAS) model. Under such a model, the device manufacturer would essentially become an information technology service provider.

Software for remote patient monitoring will become more and more important and acquire more functionalities, such as functionality that decides whether or not to alert the user.

New software will be developed as a result of the paradigm shift to disease prevention and have as its intended purpose to predict probability of disease (including recurrence) to support lifestyle management and/or prophylaxis. Software-based decision support systems for diagnosis will become more and more refined and embedded in hospital processes and general hospital systems such as the patient record system. Consequently, it will become more

difficult to decide what hospital system should be CE marked and what not.

Software developers will increasingly use off-the-shelf software components to build software with an intended use that qualifies it as a medical device.

Software that controls medical devices will play a more and more 'active' role as devices such as surgical robots, patient care robots and intelligent drug administration devices evolve. Thus, the range of situations that software malfunction may directly impact on the human body becomes ever wider.

Finally, there are a number of electronic health initiatives at the European level focussing on software and medical devices running software that have medical devices in their scope (e.g. clinical information systems such as medical imaging devices and remote monitoring devices)^{19, 20}.

Conclusion

The European legislator has clarified the requirements for software relating to medical devices by means of Directive 2007/47/EC. These clarifications and amendments became necessary in order to account for the fundamental technical changes that have transpired since the medical device Directives were first drafted at the beginning of the 1990s.

As a result of these amendments, software as a medical device itself or as an accessory or a component or an integral part of a medical device is covered by the Directives and must comply with the requirements set forth in the respective Directives. However, only stand-alone software is directly subject to the Directive. In the case of embedded software, the conformity assessment of the software is part of the conformity assessment of the overall medical device.

In practice, manufacturers of medical devices will have to consider exactly which conformity assessment procedure is adequate for the assessment of software. Traditional testing and assessment procedures might not be sufficient for today's complex software.

However, manufacturers will be able to rely on the existing harmonised and non-harmonised standards and guidelines that have been

published recently. When thinking about compliance with the requirements set forth in the medical device Directives, manufacturers ought to be aware of the fact that testing software which relates to medical devices might be a clinical trial and therefore needs to be conducted in compliance with the applicable requirements. With regard to changes to the software during its lifecycle, manufacturers might be subject to documentation, approval and reporting obligations. In some cases, a new conformity assessment might also become necessary.

One question that remains difficult to answer in practice is where the medical device ends and where a network or other software begins. Clarification will have to follow in order to provide certainty to manufacturers in the form of MEDDEVs.

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Dr Mathias Klümper is a Partner at Lützeler und Partner, Rechtsanwälte, Gerricusplatz 24/25, 40625 Düsseldorf, Germany (tel: +49 40 98761328; email: mathias.kluemper@luetzeler.eu) and **Erik Vollebregt** is Of Counsel at Greenberg Traurig LLP, Strawinskylaan 3127, 1077 ZX Amsterdam, the Netherlands (tel: +31 20 301 7436; email: vollebregte@eu.gtlaw.com).