White Paper

The Medical Computer as A Medical Device: What Do You Need to Be Mindful Of?

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Tuesday morning, operating theatre 3 in the General Surgery department of the Hanover Medical School. About a quarter of an hour ago, the second patient was routinely prepared for their operation according to the surgery plan and is now lying on the operating table, covered by surgical drapes. Only their head and part of their shoulders are still protruding, so that Dr Peter M., the anaesthetist responsible for the operation, can monitor and control the progress of the anaesthesia.

To this end, Dr Peter M. has placed the entire apparatus required for anaesthesia on a tower at the head of the operating table, shielded from the other members of the surgical team by drapes. As long as the operation is in progress, the sophisticated medical technology relieves him of much of his work. This also applies to the medical computer mounted on the side of the tower of the anaesthesia machine, which will, virtually automatically, provide the always necessary documentation of the course of the operation. In the process it will be "fed": with data from the monitoring units of the anaesthesia technology and the supplementary data from the anaesthetist, who enters this data via touchscreen and monitors the computer.

What constitutes a medical computer?

A computer is used for these and many other purposes in the medical technology environment, including for medical technology, even if it does not immediately have an obvious therapeutic effect. In terms of medical technology, medical computers used in a sensitive, critical environment such as an operating theatre are best compared to a surgical light: on the one hand, it's impossible to imagine an operating theatre without it, but it also has no direct influence on the course of an operation or treatment itself. Of course, nobody would think that a surgical light would not have to comply with all the relevant regulations for medical technology products.

Amazingly, this clarity doesn't exist for medical computers – or at least not yet. According to the existing regulations, regardless of whether the "old" European directives[1] or the current EU regulations[2] are considered, it is essentially the intended purpose that a manufacturer assigns to their product (with plausible reasoning) that decides whether it is a medical device or not. Only if this is answered in the affirmative – of course on the basis of

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the objective definition criteria at the given point in the Medical Devices Regulation – do the regulations for medical devices take effect. Otherwise, products whose intended purpose do not define an application in connection with the medical treatment of humans are subject to other regulations in order to fulfil the requisite product safety.

Currently, there are twenty or more manufacturers active in Germany and Europe that market products under the name "medical computer". However, as things stand at the moment there are actually only two manufacturers whose medical computer products have a CE mark in accordance with the existing strict regulations for medical devices so as to prove market conformity.

Medical computers whose CE mark does not refer to the Medical Devices Regulation are therefore not per se to be regarded as not or less safe in terms of technical safety. However, a number of regulatory requirements imposed on medical devices do not apply to these products. In addition, the regulations also impose requirements on the medical device manufacturer itself which must be met. The other manufacturers are not affected by this.

The much more extensive regulatory requirements for medical devices and their manufacturers aim for a stringent, comprehensive protection of patients, users and third parties. As a result of the latest amendment to the EU Medical Devices Regulation, which is already officially in force and is (there are still transitional periods) to be applied on a mandatory basis from 26/5/2021[3] at the latest, the regulatory requirements have been further extended and in many places tightened up compared to the regulations previously based on the EU Directives.

Regulatory requirements for medical computers

It is not intended and not possible at this point to go into all the details of the regulatory provisions and the resulting, incredibly complex consequences for medical devices and medical device manufacturers. This would make for a thick tome and quickly become boring for the reader searching for the essential information. In order to be able to present this essential information, it's necessary to agree on some definitions. So as not to confuse, the following comparative observations will be presented in a highly abbreviated form and in simplified, largely not-formally-correct regulatory or legal formulations.

The regulatory requirements resulting from the newer European Medical Devices Regulation (abbreviated as MDR[4]) will be considered; the regulations of the previous directives, which are still formally applicable, are immaterial here. When we speak below of manufacturers of medical devices (abbreviated as MD manufacturers), manufacturers whose medical computer products bear a CE marking according to the MDR should be understood in the following observations. When the term manufacturer is used in the following, this refers to those manufacturers whose products – although very often also marketed as medical computers – bear a CE marking that refers to the regulations that are then applicable, such as the Low Voltage Directive, the EMC Directive or others.



Since the term "medical computer" has become established both within the industry and within the relevant user groups for a certain type of computer product with technical features that differ from those of "standard" computers for the consumer market, for instance, a delimiting linguistic definition is also required in this regard for comparative considerations. For this reason, the term will only continue to be used here for the medical panel computers of medical device manufacturers. The manufacturers whose products are not labelled in accordance with the MDR are to be referred to in the following with the abbreviation PC (for panel computer) for better recognisability.

The MDR dedicates a separate article to the "General Obligations of Manufacturers", which sets out binding specifications for MD manufacturers and that are not contained in this very specific form in regulations addressed to (non-MD) manufacturers.

Through the MDR, MD manufacturers are now explicitly obliged to set up and maintain a quality assurance system for their own companies in accordance with the EN13485 standard and to introduce, implement, document and update a risk management system according to the EN 14971 standard. Even before the MDR, it was practically impossible for MD manufacturers to do without a CE-compliant marking as a MD, but at least the theoretical possibility existed to ensure conformity by other means.

As is now the case under the MDR, PC manufacturers are not obliged to do so. The same applies to the registration obligations (also those existing before the MDR) for supervisory authorities/ institutions. Both the MD manufacturer itself and the MDs must be registered according to a defined procedure; the same does not apply to PC manufacturers.

With the MDR, there will be an additional requirement in the future (after transitional periods have expired) that medical devices must be assigned an individual, so-called UDI (unique device identifier) as a unique identification, which must also be deposited with official bodies. With the help of this UDI, extended possibilities for monitoring and control then exist. It's obvious that this will mean considerable additional administrative and practical hassle for MD manufacturers.

Furthermore, the MDR contains stipulations that specifically oblige the MD manufacturer to maintain a transparently documented market observation and monitoring system and to take precautions so as to be able to cover potential liability claims from outside if necessary. Though this is really a matter of course that every serious company will already comply with in its own interests, it's unusual that it's already explicitly and bindingly stipulated for MD and MD manufacturers in the "basic" regulation.

With regard to MD themselves, there are also significantly higher regulatory requirements from the MDR than is the case with regulatory requirements for products from other manufacturers. The associated product documentation that must be drawn up bindingly for medical devices is specified by the MDR much more extensively and also much more firmly than for other products.

As a manufacturer of MDs, one is also obliged to conduct a clinical evaluation for your own MDs. To put it very simply, this should provide evidence that the medical device actually has the performance capacity that has been assured by the MD manufacturer, without any harmful, or even possibly occurring, yet unavoidable negative effects (a striking example: X-ray radiation). If it has such side-effects, the benefits should outweigh such disadvantages.

What's more in the case of medical computers, the relevant provisions to be complied with for the CE marking of PCs are integrated anyway by existing links from the MDR for medical computers. In concrete terms, this means that, for example, the requirements regarding EMC and electrical safety, which would already allow PCs to enter the market in conformity with the regulations, must of course also be fulfilled by medical computers – independently of and supplementary to the additional requirements to be fulfilled for MD.

MDR instead of just CE

As mentioned at the beginning, the descriptions for the existing, more stringent regulatory requirements for MD / medical computers are described here in a very abbreviated form. Of course, this inevitably raises the question why a manufacturer like ADLINK submits to these for their own medical computers, when access to the market by means of a (more straightforward) CE marking as a PC would also be possible? Wouldn't it be reasonable to assume that a CE marking as a MD would give it an economically exploitable advantage over its competitors?

Well, at least the latter can be unequivocally answered in the negative. It is simply prohibited or not possible, simply on the basis of the existing regulations and also on the basis of already settled legal interpretation, to obtain a CE marking according to the MDR (formerly MDD) solely on the basis of a manufacturer's financial interests. Furthermore, from the manufacturer's point of view, it is by no means overly attractive to pursue such an objective. Finally, the potential additional revenue that could be achieved by marketing as a MD (because the MD would allegedly be more attractive for customers) would have to exceed the effort required to comply with all of the regulatory requirements compared to marketing as a PC (which ultimately also means revenue). This calculation would be risky, at least from an entrepreneurial point of view, and, since as mentioned it isn't legal, it would be unacceptable for a respectable company anyway.

It is certainly in the interest of ADLINK customers to obtain a medical computer with the CE marking as a MD; but more on this below. There is also an interest for the manufacturer itself to obtain CE conformity according to the MDR: after all, this is a visible demonstration to the outside world that adequate product safety has been ensured and that the use of the medical computer is justified even in the most sensitive areas of a healthcare facility (operating theatre, intensive care unit etc., but also for instance sterile supply rooms etc.). In the event (which of course every manufacturer would prefer not to know) that an incident occurs in which their own product may have played a role, it would ultimately be disadvantageous from the manufacturer's point of view if doubts were to already exist about the basic properties of their product.

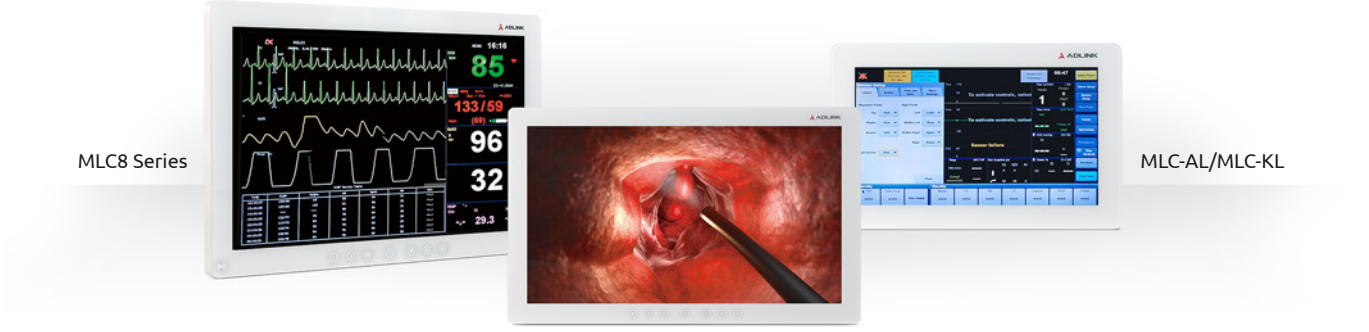
Regulatory requirements for healthcare facilities

The circle of end users who use medical computers, i.e. hospitals and healthcare institutions in general, are in turn themselves confronted with a multitude of rules and regulations. These include, of course, those aimed at ensuring a correspondingly high level of security[5], especially for patients and their own staff.

In this respect, the end customer, the hospital, has a strong interest in using if possible only those products that enable them as a responsible operator to prove with comparative ease that they have fulfilled the applicable regulations regarding the safety of the products used – especially in those sensitive areas. In the case of the question of using a PC in an operating theatre, the operator would have to carry out a corresponding risk assessment and evaluation themselves as to whether the PC product might be used or not. If the medical computer is demonstrably a medical device, the operator has already fulfilled their obligation.

The same applies if the customer for the medical computer is not an end customer but another company that itself manufactures medical devices. There are a variety of applications where the integration of a medical computer into a medical device system as a component is necessary or useful. Now, of course, the manufacturer of such a system must themselves meet all regulatory requirements with regard to their own MD. It is easy to understand that the medical device manufacturer of the system doesn't want to put the purchased components that are in use through the conformity process themselves and prefers to rely on a component that already complies with the regulations.

In conclusion, let's look back to the beginning of this text, to the comparative approach with the surgical light. Since each of the parties involved here would be better served comparatively if a "real" medical computer could be used instead of a PC, one could argue that medical computers, according to this designation, should in principle also be "official" medical devices. However, it is rather unlikely that any action will arise in this respect from the regulator's side and that this will be reflected in any form in the MDR or collateral regulations. It's therefore advisable for medical computer users in the medium and long term to pay particular attention, based on the declaration of conformity, to exactly what the existing CE marking refers to.



[1] Directives 93/42 EEC (MDD; for medical devices), 98/79 EG (IVDD; for in vitro diagnostics) et al.
[2] Regulations EU 2017/745 (on medical devices) and EU 2017/746 (on IVD).
[3] Due to the actual Covid19 crisis, the European Commission decided to postpone the applicability of the MDR for one year, i.e. from initially 26.05.2020 to 2021
[4] From the English abbreviation **M**edical **D**evice **R**egulation
[5] In Germany, for instance, the German "Medizinprodukte-Betreiberverordnung", translated as Medical Device Operator Regulation et al.

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