FAQ on CE MARK and ISO

This document outlines MetaSystems position on using computer hardware other than specified in the quotations made by MetaSystems.

Are MetaSystems imaging products CE marked?

Yes, all the imaging systems manufactured and commercialized by MetaSystems inside the European Union are CE-marked according to the IVD DIRECTIVE 98/79/EC and in future according to the new REGULATION (EU) 2017/746 on 'in vitro diagnostic medical devices'. It is important to understand that CE conformity is not automatically achieved by assembling the system from components having individual CE marks already. One of the prime requirements of the DIRECTIVE 98/79/EC and REGULATION (EU) 2017/746 is that a complete system has to be subjected to the required test procedures (see below) before it may be CE marked.

Which are the consequences for MetaSystems imaging products being 'in vitro diagnostic medical device' according to the IVD DIRECTIVE 98/79/EC and in future according to the REGULATION (EU) 2017/746?

The IVD DIRECTIVE 98/79/EC and REGULATION (EU) 2017/746 on 'in vitro diagnostic medical devices' have several consequences for MetaSystems to comply with the regulations:

- MetaSystems is registered at the German competent authority for 'in vitro diagnostic medical devices' and if required as well with the authorities of other EU member states.
- MetaSystems has implemented a quality management system (QMS) in line with EU, ISO Standard and FDA (Federal Drug Administration USA) regulations. The QMS includes e.g. validation of suppliers, extensive software and hardware tests, risk assessment and effective complaint handling procedures.
- Any new imaging system configuration (PC, camera, mot. microscope stage, stage controller boards, etc.) is subjected to electrostatic and electromagnetic compatibility measurements in a certified laboratory as required for CE conformity.
- The published REGULATION (EU) 2017/746 can lead to a higher risk class of the MetaSystems imaging system products. Therefore, the Systems might need to be certified by a notified body under the REGULATION (EU) 2017/746 in the near future.
- The compliance of MetaSystems with the rules of the DIRECTIVE 98/79/EC and REGULATION (EU) 2017/746 can be audited at any time by the competent authority.

MetaSystems
info@metasystems-international.com
www.metasystems-international.com

Are customers allowed to assemble systems on their own using MetaSystems components?

Yes, but such a system cannot be CE marked by law. We can only CE-mark systems manufactured by MetaSystems using approved components. Although MetaSystems can provide 'kits' (for example comprising of a camera and software), any system assembled from these kits and a non-approved PC will NOT fulfill conformity rules according to the DIRECTIVE 98/79/EC and REGULATION (EU) 2017/746. In this instance, MetaSystems is merely a supplier, but not the system manufacturer.

Under certain conditions, a CE mark is not required for an 'in vitro diagnostic medical devices':

According to the REGULATION (EU) 2017/746, Article 5 (5), with the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity;

(b) manufacture and use of the devices occur under appropriate quality management systems;

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;

(d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

(e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(f) the health institution draws up a declaration which it shall make publicly available, including:

(i) the name and address of the manufacturing health institution,

(ii) the details necessary to identify the devices,

(iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;

If the customers' device will be used 'for research use only' according to the 'IVD Guidance: Research Use Only Products (MEDDEV 2.14/2 rev.1), other CE conformity procedure may apply.
In any way, achieving CE conformity is a labor-intensive and costly process, minimizing any potential cost saving from purchasing components form a third party.

MetaSystems
info@metasystems-international.com
www.metasystems-international.com

Will MetaSystems support any system assembled from a 'kit'

If you decide to assemble a system from MetaSystems 'kits' and other components, we can provide technical assistance in setting up the system. All cost for an on-site support will be charged. Providing support does not imply that MetaSystems becomes the manufacturer of the system. The legal responsibility for the system still lies with your institution.

Will MetaSystems' warranty cover also systems including 'kits'

Supporting systems of mixed origin is always difficult. When problems occur, it is often difficult to link an observed failure unambiguously to a certain hardware or software component. It is evident, that we can only take responsibility for systems or components provided by MetaSystems. We will admit any warranty claims for these parts only. Any service for other components must be arranged separately. We strongly recommend to set up a plan covering the following issues:

- Is it possible to send the system to MetaSystems for repair or is an on-site service needed (workload, turn around time)?
- Is a remote access possible, e.g., with TeamViewer Software? An access approval is needed from the customer's side.
- Do you need a replacement system while your system is on repair?
- Is there a complete documentation available for the system (incl. operating systems service releases and patches, all additional software (drivers), and license codes)?
- Is there a budget allocated for the repair and any potential additional technical assistance required?

What does DIN EN ISO 13485 and DIN EN ISO 9001 stand for and does MetaSystems fulfill the ISO requirements

The International Organization for Standardization (ISO) is an international standard setting body. Standards ensure desirable characteristics of product and services such as quality, environmental friendliness, safety, reliability, efficiency and interchangeability, and at an economical cost.

DIN EN ISO 13485 fulfills the DIRECTIVE 98/79/EC and REGULATION (EU) 2017/746 on 'in vitro diagnostic medical devices'. It specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

MetaSystems is regularly audited and certified to be in conformance with DIN EN ISO 13485 (valid version). Copies of the MetaSystems ISO certificate are available on request.

The ISO 9001 is the standard for quality management system, on which ISO 13485 is based on. Therefore, ISO 9001 is not sufficient for producers of medical devices like MetaSystems.

MetaSystems
info@metasystems-international.com
www.metasystems-international.com