CE Mark for MetaSystems Products

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

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;

In practice, a CE mark is not required, if the health institution fulfil the requirements as stated above.

MetaSystems
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MetaSystems installation using customer components

A system incorporating non-approved components cannot be CE marked by law! MetaSystems can only CE-mark systems manufactured by MetaSystems, using approved components. If a system has been built using major components (such as camera, PC, microscope stage or microscope) not within the approved standard specification of MetaSystems, this system will NOT comply with 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 manufacturer of the system.

MetaSystems can provide technical assistance in setting up a system that includes customer components. Providing support does not imply that MetaSystems becomes the manufacturer of the system. The legal responsibility for such a system still lies with the institution of the manufacturer.

The support of systems including customer components is always difficult; failure analysis and trouble shooting will be more complicated and time consuming as compared to the validated standard configuration.

MetaSystems will assume responsibility for components provided by MetaSystems only. Warranty will also be limited to components delivered by MetaSystems. Any service that may be required due to malfunction or compatibility problems of customer components will be charged to the customer.

We acknowledge: the CE mark of MetaSystems products built with customer components is subject to restriction.

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Place Date Customer Name (Print) Signature

CE MARK