CE Marking

Before entering the European market or to be precise, the European Economic Area, software that is defines as a medical device must be CE marked. The European Economic Area consists of all 28 member states of the European Union EU and 3 of the 4 member states of the European Free Trade Association EFTA: Iceland, Liechtenstein and Norway.

The CE mark can only be obtained by complying to the **European Medical Devices Regulation (2017/745/EC)[1]** in short, the MDR. Be aware that the manufacturer (see definition below), is responsible for obtaining the CE mark, not a supplier of software to that manufacturer.

> a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

Of course, the software supplier must develop its software according to the MDR, but in the end, the manufacturer will appear in front of a court of law if he did not follow the MDR and patients were injured or even worse died due to usage of his product.

This chapter will provide an overview of the steps to take to enter the European market as a medical software device: the CE submission.

Software for IVD applications (providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations) is out of scope. For this type of software (In Vitro Diagnostic Regulation 2017/746/EC) is applicable.

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[1] Currently (2018) the predecessor of the MDR the Medical Device Directive 93/42/EEC (MDD) is also valid. The MDR is mandatory from May 2020 onwards and the MDD is then obsolete.