Regulation of medical devices

Drag the words to correct boxes.

Many items can be considered to be medical devices according the *medical device regulation* of the European Union. This includes, for example, different instruments, implant and *software* product that are used for activities such as *monitoring*, diagnostics, treatment of *diseases* and injuries. Products which achieve these activities purely by *pharmacological* or immunological means, are excluded from this definition, however, such functions can be *included* in devices that are considered to be medical devices.

In EU, there are two main regulations in place dealing with the regulation of medical devices in EU are: the Medical Devices Regulation and the *In Vitro Diagnostic* Medical Devices Regulation. The term “regulation” refers to a legal act of the European Union that becomes immediately enforceable as *law* in all member states simultaneously. Regulation of medical devices is important because it helps to ensure users’ access to products that are reliable and *safe* to use. *CE marking* indicates that the product conforms to health and safety standard of European Economic Area and it is required for medical devices in order to enter the market. Depending on the risk class of a medical device it can be acquired by either self-declaration or by undergoing *an audit process* by *a notified body*.