

Wellsystem_MEDICAL

Abidance by the law for medical devices

Medical device

"Medical devices must provide a high-grade protection for patients, users and third persons and they must achieve the performance declared by the manufacturer"

Licensure for medical devices according to MPG class IIa!

Wellsystem, respectively JK_Products as manufacturer, is being monitored and checked on the existing regulations for medical devices regularly by an accredited ("appointed") inspection authority. Other manufacturers of active therapeutical devices can feign to have a licence by attaching a CE mark without a number. However, a medical device, for class IIa devices, is only inspected and licensed if it carries a CE mark with the number of the "appointed inspection authority" (= inspection authority accredited by the EU). It is regulated by law, directive 93/42/EEG, that the CE mark with the code number of the "appointed inspection authority" must be placed on the device clearly visible, as well as in the instruction manual. The inspection authority responsible for the monitoring of the Wellsystem_MEDICAL has the code number 0197; it is to be found next to the CE mark on page 51 of the instruction manual, on the type plate, as well as on the TÜV certificate and the declaration of EC conformity.

Why is this licence necessary?

If you as a doctor or alternative practitioner use a device on your patients for diagnostics or therapy in your practice, this device has to have a licence as medical device. This licence has to conform with the regulations of the MPG (law for medical devices).

What happens if I buy an unlicensed system and treat my patients with it?

Using a medical device on humans that is not licensed for the EU makes one incur a penalty and in case of a recourse claim the practice insurance does not cover any costs. Possibly the device used for the treatment is being seized by the authorities and tough fines are imposed. In certain cases it can lead to an occupational ban. Therefore, if you buy a medical device, pay attention to the licence first, then to the performance and finally to the price.