

## **FAQs**

### **Are AUER Staircrawlers medical devices or not?**

Occasionally provide customers and users, as well as those in the tendering and procurement involved institutions, insurance companies and government agencies, the question of the existing certification of products. This certification as a medical device according to MPG often is provided ultimately in tenders condition.

### **MPG Medical Devices Act / Scope**

In the latest version of the European Medical Devices Act (MPG), the law imputed products clearly are defined in § 3:

#### **§ 3 Definitions**

1. Medical devices are all the instruments alone or in combination, apparatuses, devices, software, materials and preparations made from substances or other objects, including the software intended by its manufacturer to be used for diagnostic or therapeutic purposes and necessary for the proper functioning of the medical device software from the manufacturer for application to humans by means of their functions for the purpose

- a) the diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- c) the investigation, replacement or modification of the anatomy or of a physiological process, or
- d) birth control

are intended to serve and whose **principal intended action in or on the human body is achieved** either by pharmacological or immunological metabolic means, their mode of action may be assisted by such means. /....

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**From the above definitions it is clear that our products are never classified as medical devices and not can be certified, as its principal intended action is achieved neither in nor on the human body, but is limited exclusively to a pure transport purposes.**

**If the part of the buyer requires certification as a medical device and / or if this is offered by other suppliers, this would not be allowed!**

Subject of ev. specific provisions in individual countries thus only a **CE certification according to the Machinery Directive (MRL)** is permitted which have all of our products in general!