



The CE mark and the classification

All medical equipment has to meet certain classification regulations. The EC directives for medical equipment (93/42/EEC) distinguish between four classes (I, IIa, IIb, and III), which the medical equipment must be assigned to. The manufacturers are obliged to classify their products according to the risk classes, class I has got the lowest and class III the highest risk potential.

Because our foot- and hand-operated control devices for electro-medical devices also come within the purview of the Medical Device Directive, our medical equipment is classified accordingly.

The design engineers and product managers for medical equipment have adhered carefully to the standards and directives valid for our products for years. How we proceed, which standards we must observe and which future developments might be realized in this difficult-to-analyze field, are explained shortly and in summary in the appendix following this catalog.

According to the MDD accessories have to be treated in the same way as the medical devices. Accessories are objects, materials, preparations like software, which are not a medical device itself, but are destined by the manufacturer to be applied in conjunction with a medical device, in order to apply these according to their destination or to support the destination determined for the medical device.

Our switchgear control medical devices – in combination with the control unit connected by the customer – according to their destination. They are classified as accessories and must be equipped with a CE mark according to the MDD.

The series KF-MED, for example, meets all relevant conditions that result from the Medical Device Directive (Directive 93/42/EEC), the standard IEC 60 601 and class AP. Furthermore protection classes up to IP X8 per IEC 60529 are achieved with this series.

In order to meet the high quality and safety requirements for medical equipment, we submit as a manufacturer of medical equipment to an additional voluntary safety examination by a competent authority (notified body).

The safety examination contains a type test of the product on the basis of European harmonized standards, a plausibility test of the prescribed conformity process for the CE mark, including the technical documentation according to the EC directive and a factory inspection with repeated production controls.

These additional voluntary safety controls are marked on our foot controls with the GM mark (approved medical device) placed by the TÜV.