

Categorization of clinical trials with medical devices

(according to Article 6 ClinO-MD)

clinical trials with medical devices

Category A

The device bears a CE mark, is used according to the instructions for use and is not forbidden in Switzerland.

Subcategory A1

Participating persons **will not be subjected to additional invasive or burdensome procedures** over those used under normal conditions of use of the device.

Subcategory A2

Participating persons **are subjected to additional invasive or burdensome procedures** over those used under normal conditions of use of the device.

Category C

The device does not bear a CE mark, or is not used according to the instructions for use, or is forbidden in Switzerland.

Subcategory C1

The device bears a CE mark, but is not used according to the instructions for use.

Subcategory C2

The device does not bear a CE mark.

Subcategory C3

The device is forbidden in Switzerland (making it available on the market, putting it into service or using it on a person).