

Categorisation of performance studies with in-vitro diagnostic products (in accordance with Art. 6a ClinO-MD)

Performance studies with in-vitro diagnostic products

Category A

Interventional study with:

- Product with conformity marking
- Product used in accordance with instructions for use
- Product that is not prohibited in Switzerland
- With and/or without procedure as per Art. 6a para. 1 letter b no. 2

Non-interventional study

Sub-category A1

Interventional study

Product carries a conformity marking, is used in accordance with instructions for use and is not prohibited in Switzerland.

Sub-category A2

Interventional study

as per Art. 6a para. 1 letter a nos 1-3

- with additional application of invasive surgical procedure for the purpose of biological sampling
- or**
- with additional invasive or stressful procedure for person affected¹.

Non-interventional study,

that does not fall under Art. 2a para. 1-3 ClinO-MD.

Category C

Interventional study with:

- Product without conformity marking
- or**
- Product not used in accordance with instructions for use
- or**
- Product that is prohibited in Switzerland

Sub-category C1

Product carries a conformity marking but is not used in accordance with instructions for use.

Sub-category C2

Product carries no conformity marking

Sub-category C3

Product is prohibited in Switzerland (prohibited to make available on the market, put into service or use).

1. As per Art. 6a para. 1 letter b no. 2