Voucher of € 5.000 for

THINC. First – CE Certification Support (€ 10.000)

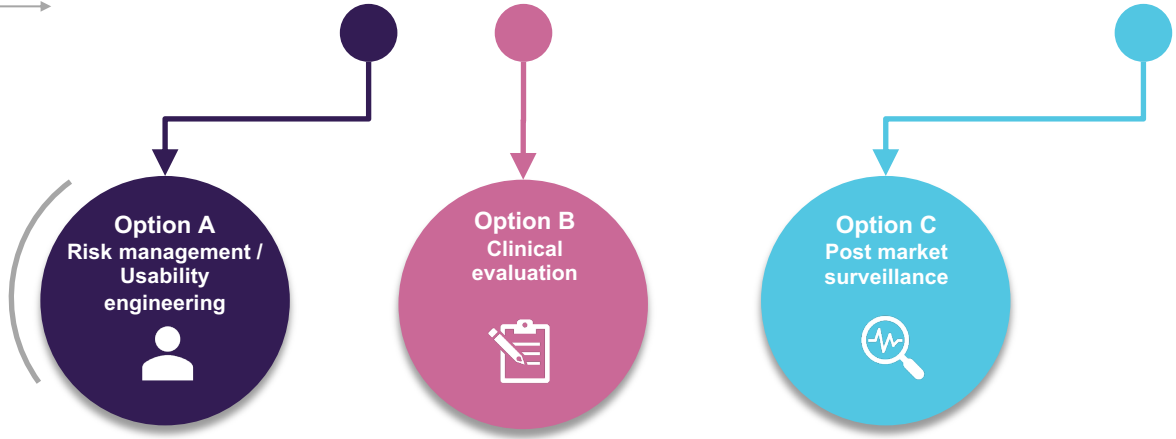
Step 1. Pressure cooker meeting

- What is the current status of your CE certification process?
- Which clinical evidence is lacking to confirm safety and performance of the medical device?

Step 2. Desk research / methodological support

We provide hands-on support in selecting the type of study design(s) required and in which order these should be conducted (evaluation roadmap). We provide essential input for the study protocol(s), i.e.:

- Study protocol template
- Study population and sampling strategies
- Design data collection & outcomes
- Design data analysis
- Reporting



(User-related) Risk analysis
Usability engineering plan

- Use specification
- Formative usability testing
- Summative usability testing

Clinical performance specification
Clinical evaluation plan, which might include:

- Systematic literature review
- Diagnostic accuracy study
- Feasibility / pilot study
- Experimental study (trial)

Post market surveillance plan:

- Data collection activities / sources
- Data collection categories / outcomes
- (Trend) analysis

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ROM Utrecht Region