

## NEWCOMER IN MEDTECH

**You are excited? You want to enter into this innovative high-tech business? You want to find your way and overcome the regulatory hurdles? You are in need of a time and cost estimate and a realistic roadmap? ... And on top of all that, just to make it fun, you have to urgently elaborate a business plan to convince investors?**

**To be successful, you need the right partner, endowed with enough strategic and practical expertise.**

**We have developed different packages that are tailored to the real needs of MedTech start-ups and any newcomers dealing with medical devices and in-vitro diagnostics.**

### What we provide

#### A basic step towards your "go-to-market" strategy

- Statement in order to define the applicable regulation and classification of your product
- Definition of pathway, e.g. conformity assessment procedure (CAP) for a CE mark
- Regulatory & Clinical Strategy Plan (RCSP)




#### Sharing of knowledge: live and interactive

- Medtech Framework Overview, including an insight into key markets (EU, US...)
- Q&A session with the ISS trainer, in English, German or French

#### Support for making informed decisions and defining a realistic planning

- Handling of your strategic burning questions by a Senior in Management consulting
- Benefit from inputs on risk mitigation, business plan, cost estimations, and market access

### What we offer

	 BASIC	 STANDARD	 ADVANCED
Regulatory statement	◆	◆	◆
Definition of pathway	◇*	◆	◆
Regulatory requirements overview, incl Q&A	-	◆	◆
Clinical development overview, incl Q&A	-	-	◆
Strategic consulting	-	6h	10h + 2h for free
Regulatory & Clinical Strategy Plan (RCSP)	-	-	◆
<b>Cost</b> (for 1st market, e.g. EU, US...)	<b>4'000.- CHF</b>	<b>9'500.- CHF</b>	<b>25'000.- CHF</b>
Each additional market	+ 2'000.- CHF	+ 3'000.- CHF	+ 10'000.- CHF

*\*only for start-ups: incl a recommendation for free (value 1'000.-)*

➔ You have the choice: from vital minimum to the best option for building a realistic roadmap

### Why ISS

#### We know how

Our solutions are lean and sustainable. Our knowledge and know-how in all key medical devices fields allow us to provide an integrated solution. Relying on many years of experience in MedTech business creation, we can confidently accompany start-ups and well-established companies moving towards this challenging field.

#### Services tailored to your needs and resources

Your benefit is the most important part of our services. Therefore, we are offering different packages to make sure you find the right balance between your most urgent needs and what you can afford. We are happy to advise you personally to find the best solution for you.

#### A strategic partner with a team dedicated to your project

We commit to focus on your product, your wishes and constraints, and exploit all the synergies of our teams in order to design for you a well fitted pathway to your market, worldwide. Some of our experts are also Innosuisse coaches

#### Contact

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