CARAG
leading medtech engineers

# Marketing approval

## Challenge »

The path to CE marking is time-consuming and costly. Manufacturers of medical devices face a maze of standards and other regulatory requirements.

$$f(x) = \frac{1}{\sigma\sqrt{2\pi}} e^{-\frac{(x-\mu)^2}{2\sigma^2}}$$

## Approach »

Systematic assessment of conformity by experienced engineers and technicians based on controlled, certified processes.

## Services »

- **Conformity assessment.** Meeting the essential requirements is a prerequisite for introducing your medical devices to the market. We will assist you with systematic conformity assessment.
- **Technical documentation.** The technical documentation is your proof that your medical device meets the General Safety and Performance Requirements (GSPR). We will assist you with structuring, issuing, and the periodic review of your technical documentation.
- **Harmonized standards.** The identification of the harmonized standards to be applied must take place at an early stage so that the standards can be incorporated into the development of new products.
- **Classification.** We will advise you on how to allocate your product to the relevant regulation and on the classification of your medical devices pursuant to Annex VIII of Regulation (EU) 2017/745 on medical devices (MDR).
- **Risk management.** Together with your specialists, we will compile a tailor-made risk management process pursuant to EN ISO 14971.
- **Clinical evaluations.** We will show you how to conduct your clinical evaluations in accordance with Article 61 and Annex XIV of Regulation (EU) 2017/745 on medical devices (MDR).
- **Clinical trials.** Clinical trials must be planned and conducted in accordance with the principles of Good Clinical Practice (GCP) and EN ISO 14155. We will show you what to pay attention to in the process so as to meet regulatory requirements for approval.
- **Training.** We will conduct on-site training for specific topics for your staff members.

## Trust »

Since 1999, we have been focusing on the development of high-quality medical devices. This is why we are very familiar with the path through the maze of standards and regulations. We have proven repeatedly that we can successfully introduce devices of all risk classes to the market. All of our processes are certified in accordance with EN ISO 13485.

## Uniqueness »

A leading interdisciplinary team in Switzerland is working for you – practically based and target-oriented.

## Do you wish to obtain marketing approval for your new device quickly and efficiently?

## Contact »

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Carag »

Carag is a leading Swiss engineering company and point of contact for physicians and medtech companies developing high-quality products for cutting-edge medical applications. Carag has an experienced, performance-driven, interdisciplinary team of engineers, physicians, medical technicians, electronic technicians and software developers. The broad range of specialized engineering and consulting services starts with technical feasibility checks and continues with product development through marketing approvals, regardless of the regulatory complexity.