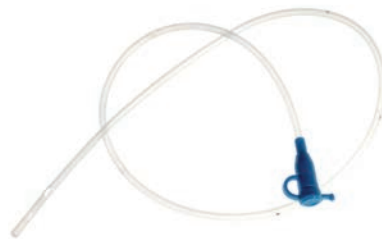
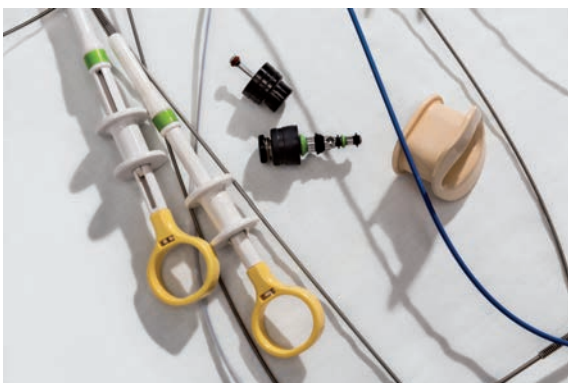
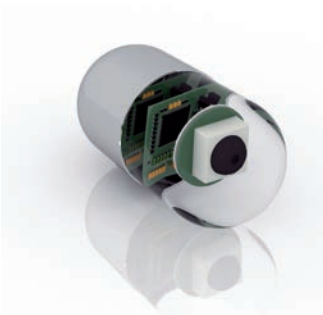
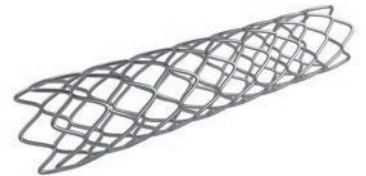


## Ready for the future...

... and the forthcoming regulatory requirements



New challenges facing the development of medical devices

The new **Medical Device Regulation** (MDR) - EU Regulation 2017/745 on Medical Devices - came into force on 25th May, 2017. Following a transitional period, application is mandatory as of 26th May, 2020.

## **The demands on the scope of clinical data are significantly increased by MDR.**

In order to prove conformity with MDR and thus obtain certification, manufacturers must have a quality management system in place. Clinical post-marketing monitoring of the products after they have been placed on the market is an essential part of this quality management system. The requirements of the MDR will also apply to old products from 26th May, 2020.

Our Services:

- **Analysis of existing Documentation**
- **Project Management**
- **Study Planning**
- **Study Execution**
- **Monitoring**
- **Data Collection / Data Management**
- **Evaluation**
- **Preparation of Registration Documents**

We would be pleased to support you in implementing the requirements necessitated by the new regulations. Together with our partners, we are in a position to offer you tailor-made modular solutions that are closely oriented to your individual needs. We recognize the challenges and would welcome the opportunity to support you, with our many years of experience, in implementing these extensive tasks.

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