

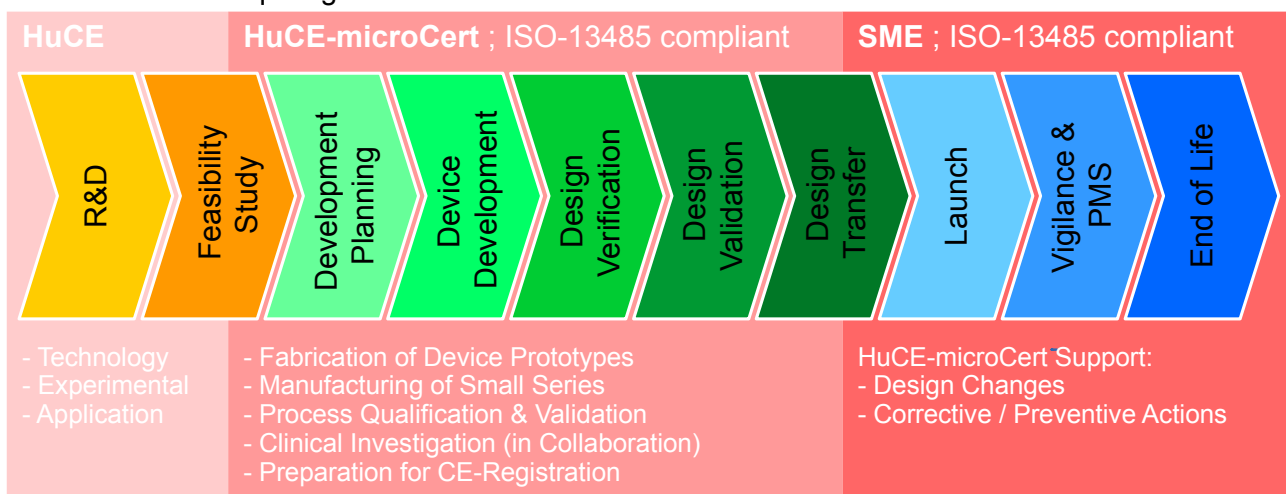
Quality Matters - Institute HuCE at BFH is ISO-13485 certified

1st university (of applied sciences) in continental Europe
to be ISO-13485 certified



Medical devices are strictly regulated by European directives to ensure efficacy and safety of the patient. Class II and III medical devices in particular ask for a quality management system in place such that the complete life cycle of a product can be controlled. However, consistently increasing requirements for market access (CE-registration) and surveillance raises the burden likewise for suppliers, manufacturers, and distributors of any kind of medical devices. Start-ups and SMEs are specifically challenged to provide adequate resources for this regulatory framework.

With the aim to comply with the medical device market, the Institute for Human Centered Engineering HuCE of the Bern University of Applied Sciences BFH has established a new group named HuCE-microCert. HuCE-microCert is committed to closely collaborate with SMEs in design, development, manufacturing, and launch of medical devices. In combination with the applied research capabilities, the institute HuCE can now offer a complete package to SMEs in the field of medical technology, from research ideas to medical compliant product development and manufacturing. On one hand, HuCE-microCert offers consistent processes guaranteeing compliance with international directives and accepted standards. On the other hand, HuCE-microCert provides the facilities needed for production of prototypes during the feasibility phase up to small series intended for design verification / validation of a medical device. Together with partners HuCE-microCert accompanies also clinical investigations, too. As first milestone, HuCE-microCert has recently been certified for its quality management system according to the international standard ISO-13485 for design and manufacture of medical devices and has setup a cleanroom ISO class 8 for production of medical devices requiring a controlled environment.



<http://www.huce.ch>

<http://www.huce.ch/microlab/research>