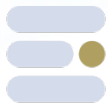




«We build Medtech & IVD Companies »

Karina Candrian

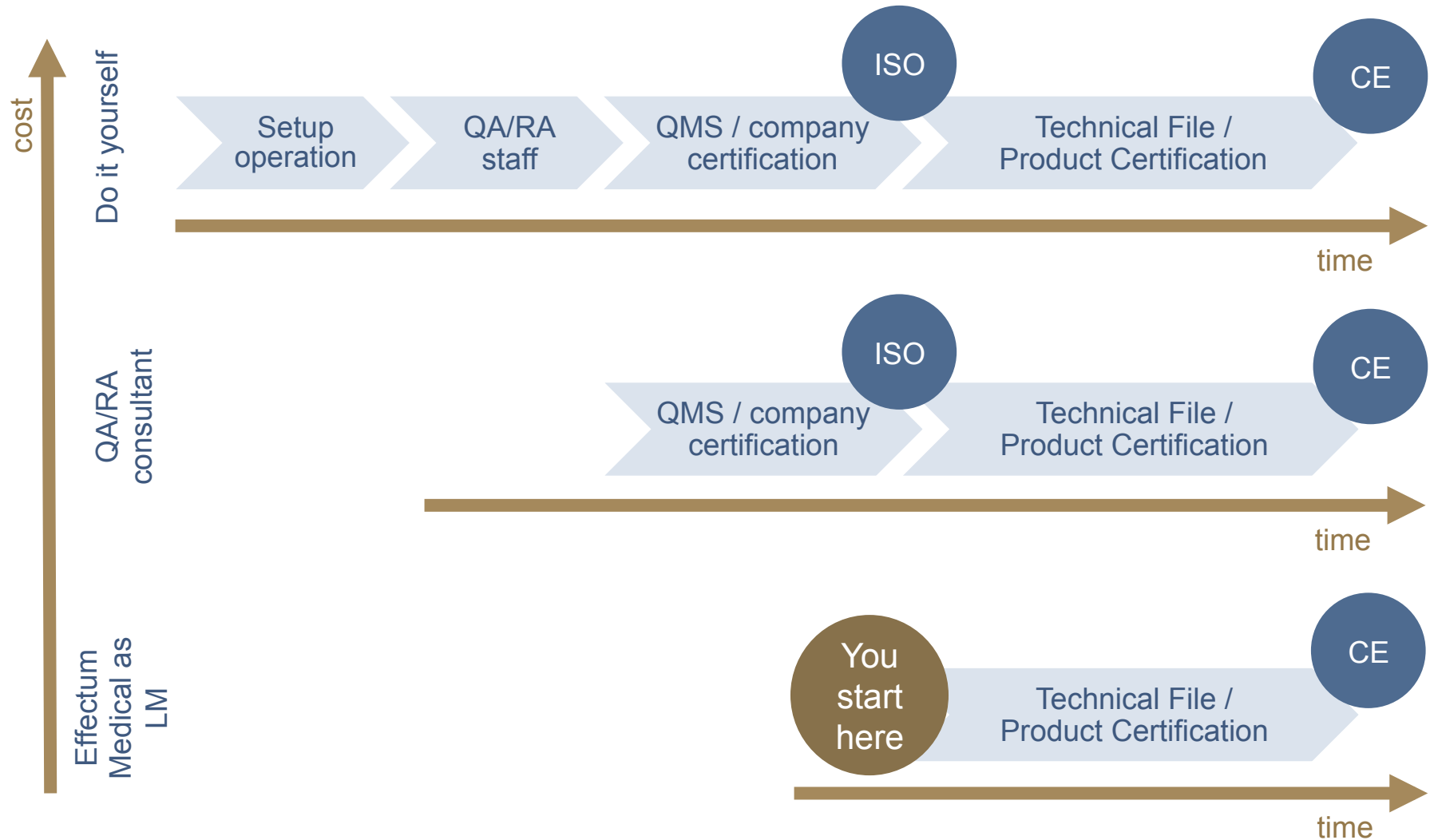
Schaffhausen, June 5, 2018



«Innovators in Medtech are having a hard time bringing new products and services to market. - That's what we change. »



« We accelerate time to market by giving our customers access to our QMS and acting as legal manufacturer »





Advantages

- You have more time to focus on value creating activities, such as product development, launch preparations, market development, marketing, and sales.
- You do not have to worry about changing norms, regulations, and deadlines.
- You do not need an own ISO certification.
- Your profit from lower costs for quality assurance as you can share them with other companies.
- You profit from faster product certification (good, existing relation/collaboration with our notified body).

Disadvantages

- Effectum Medical appears as legal manufacturer on the label (nevertheless own branding possible)



ISO Certification

- Maintenance of quality management system according to ISO standards for medical devices
- Annual ISO audits (incl. Preparation and debriefing)
- Elimination of all non-conformities from ISO audits
- Monitoring of norms and regulations, and adaptation of QM system
- Payment of all costs and fees for ISO audits
- Transfer from MDD to MDR/IVDR

Product Certification

- Upon request, preparation of or support with technical file for product certification
- Maintenance of product certification:
 - Validations
 - Post Market Surveillance
 - Change notifications
 - Supplier audits
 - Up-date of technical file
- Payment of all costs and fees for product certification
- Liability as legal manufacturer
- Re-registration according to MDR/IVDR

« Our Team Members: A interdisciplinary team with a broad range of competencies and many years of experience in medtech »



Founders & management team

Karina Candrian
CEO



Jens Richter
CTO



Nila-Pia Rähle
COO



Rolf Schmid
CFO/CMO



Team

Dr. Daniel Caminada
Diagnostics



Ulrike Neuberger
Medical Devices



Dr. Kurt Ruffieux
Dental



Reto Schöni
QM & RA



Advisory Board

Dr. Michael Ahrens



Prof. Dr. Philippe Cattin



Beat Steffen



Dr. Heiko Visarius





Financial Partners



GO BEYOND
EARLY STAGE
INVESTING

Johnson & Johnson
INNOVATION

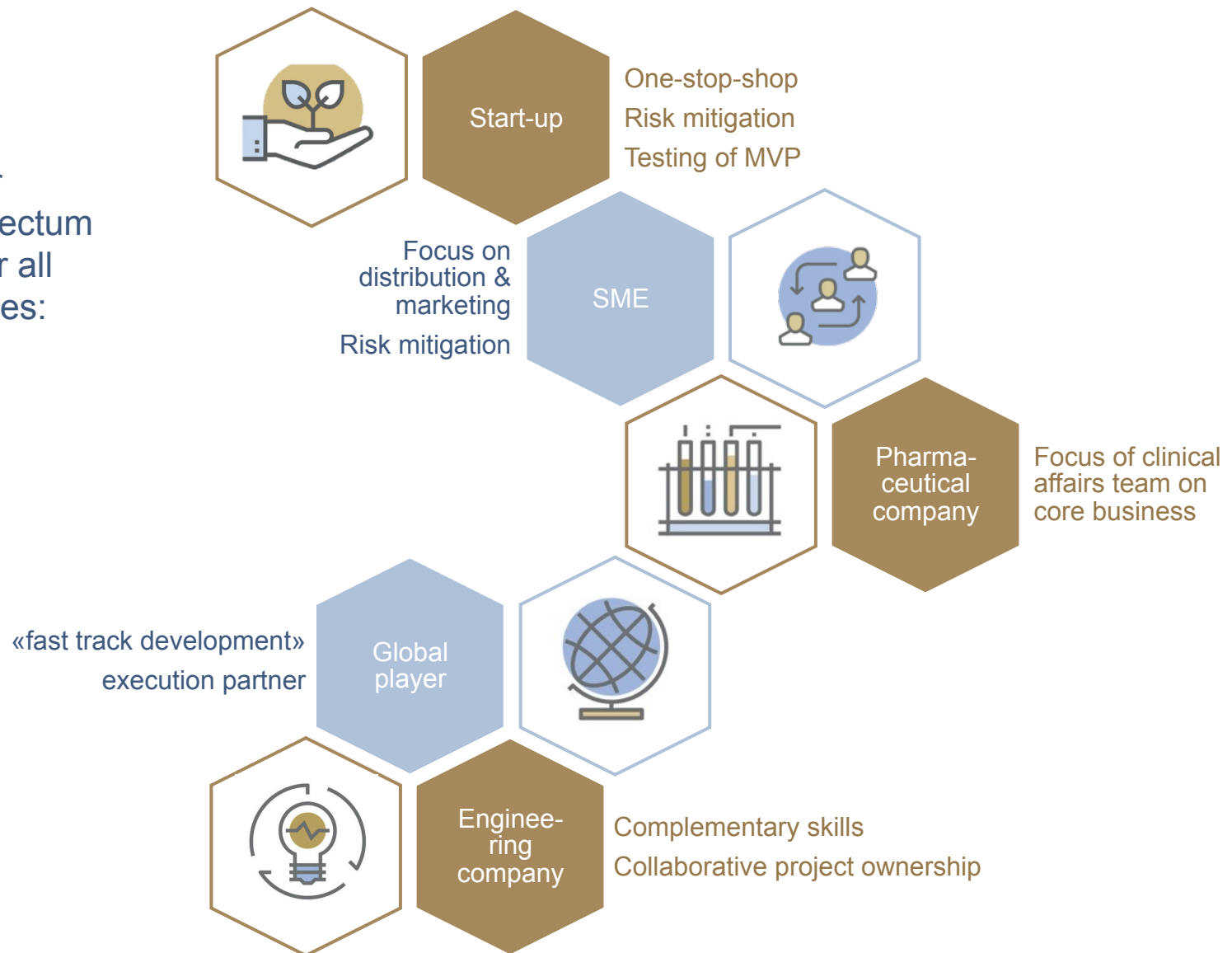
Execution Partners



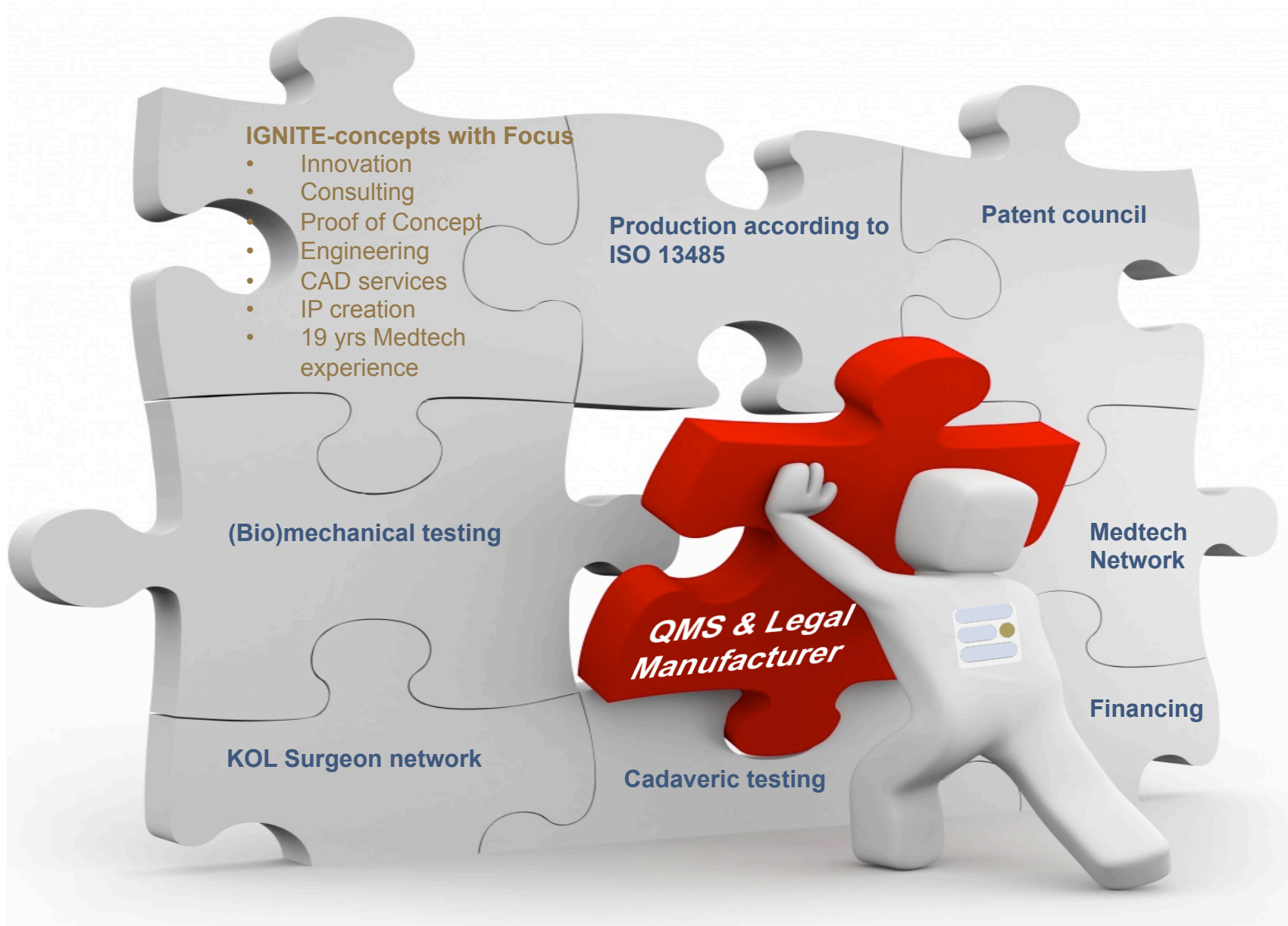
« Different Customer Profiles – different reasons for working with Effectum Medical »



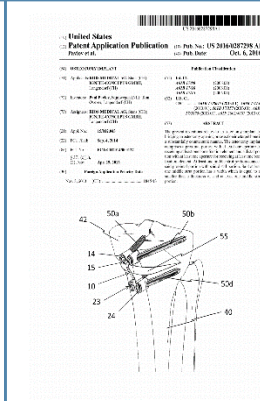
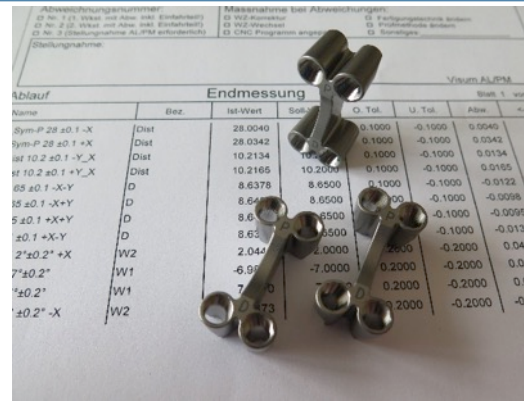
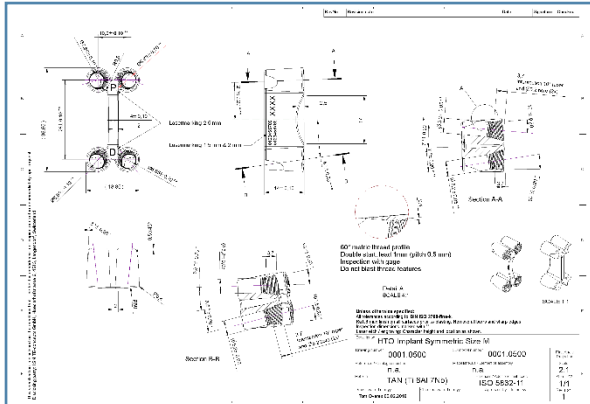
Two reasons for working with Effectum are the same for all customers profiles:
saving time
and
saving costs



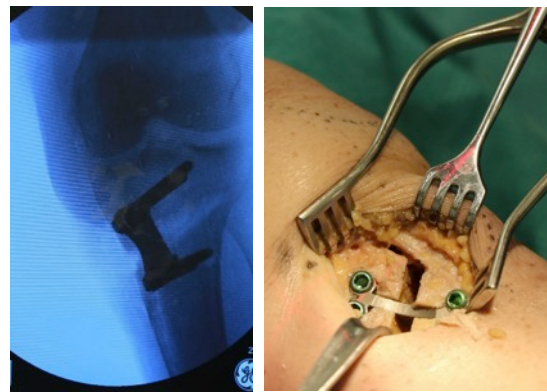
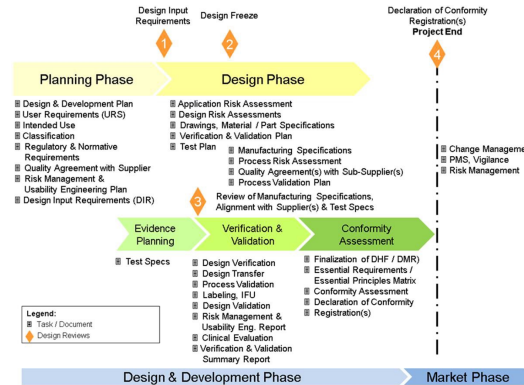
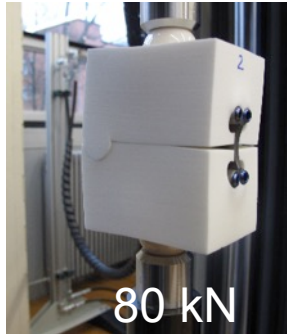
« Collaboration example - The centre piece was missing »



Project example: High tibial osteotomy



EP (B1)
JP (B2)
CN (B)
KR (B1)
US (A1)
IN (A1)
TW (A1)



« Testimonials »



Effectum Medical makes a key difference for start-ups and small companies regarding time to market and eliminates the hassle of finding a suitable Notified Body.

(Beat Steffen, Advisory Board Member)



Potential exit partners of a start-up do not want to buy costly quality and regulatory processes as they have their own. Outsourcing to Effectum Medical allows me to invest more into technology, product and IP, creating a higher return on investment.

(Dr. Kurt Ruffieux, Chromeopharm, customer of Effectum Medical)

Effectum Medical is a one-stop-shop for inventors and start-up founders of medical devices and puts the timeline on a fast track for a product from idea to market.

(Dr. Michael Ahrens, Advisory Board Member)



Effectum Medical offers complementary skills to mine, offers start-up friendly tailored solutions, and is sharing the driver-seat with me.

(Tom Overes, Ignite Concepts, Customer of Effectum Medical)



« What makes us different? »

1

You focus on your idea and core competencies - We build the company together.

2

We maintain a quality management system according to ISO standards for medical devices and IVD.

3

We share the risk by acting as legal manufacturer for your product.

4

We support you in maintaining your product registration (i.e. process validations, post market surveillance, etc.).

5

We offer organizational structure & back office services, as well as access to project financing.

Thanks for your interest!

Please contact us, we are looking forward to a fruitful collaboration!

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CH-4600 Olten

info@effectummedical.com
effectummedical.com



EFFECTUM MEDICAL
YOUR START-UP TO MARKET

