

## COMPANY

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MedFact engineering GmbH is a small, flexible and competent medical device company and started business in 2008.

MedFact is working with the latest technologies but also with proven precision engineering methods. The equipment is state of the art, including class 7 and 8 cleanrooms.

All engineers, technicians and workers are skilled, motivated and experienced for many years.

MedFact is ISO 13485 certified and FDA filed.

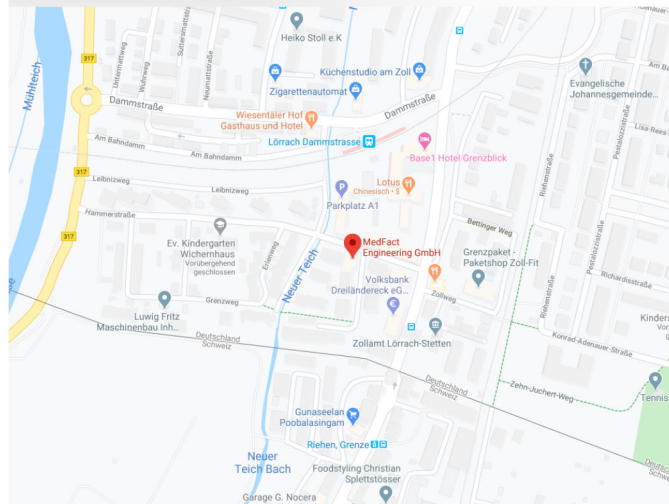


## DIRECTIONS

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MedFact engineering GmbH is located in Lörrach, Germany, a nice medium sized town at the German border to Switzerland.

You can reach us via car using the highway A98 or by train to the station "Basel, Badischer Bahnhof" and a short taxi ride. The nearest airport is EuroAirport Basel/Mulhouse/Freiburg.



### MedFact engineering GmbH

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Hammerstraße 3  
79540 Lörrach  
Deutschland

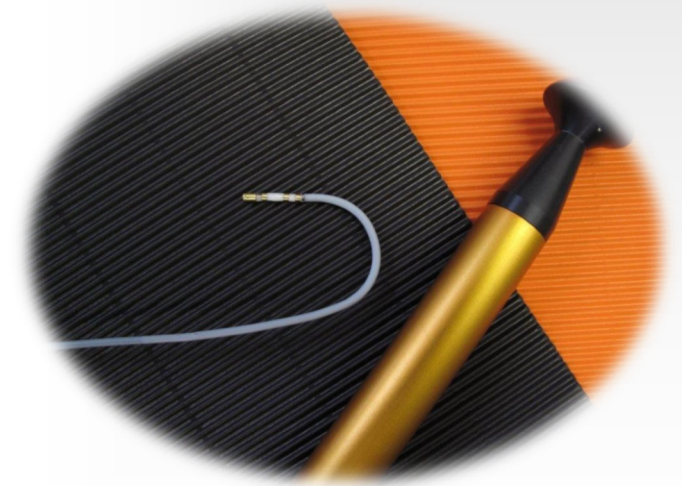
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# MedFact

engineering GmbH

## PRODUCT AND SERVICE INFORMATION

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MEDFACT. INNOVATIVE. FLEXIBLE. RELIABLE.



## MedFact products

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MedFact designs, develops and manufactures all kind of different medical devices, but has started with the development of cardiac ablation catheters and irrigation tubing sets.

Our devices are approved by our notified body and include at least the following devices

- Irrigated and non-irrigated RF ablation catheters
- Lasso/MAP mapping catheters
- Irrigation tubing sets
- Cables and adapters

For further information regarding our own devices, please check out our website [www.medfact.eu](http://www.medfact.eu) or contact us directly via email using [office@medfact.eu](mailto:office@medfact.eu).

## Customized manufacturing

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We develop and/or manufacture devices according to your specification. As we have our own development department, including a development production line, four cleanrooms and production rooms on two different sites, we are optimally equipped to provide you with a device from an idea to an approved medical device.

Since our founding in 2008, lots of other devices, aside from our own ablation and mapping catheters, have been developed and manufactured, including medical devices for the fields of :

- electrophysiology,
- neurology,
- infusion therapy,
- gastroenterology,
- gynaecology, and
- neonatology.

During development, manufacturing and the approval process our experts of the regulatory affairs department and our quality management support you as needed.

If you need a sterile packaging service our contract steriliser can be used to sterilise your device using ethylene oxide.

If you would like a list of references, please do not hesitate to contact us via email using [office@medfact.eu](mailto:office@medfact.eu).

## Service Provision

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As a contract designer and manufacturer of our own devices our team has lots of experience and is familiar and adheres to all relevant regulatory requirements, such as technical standards for your device, EN ISO 13485, EN ISO 14971, EN ISO 10993 series, and all required national and international laws, directives, regulations and guidelines.

Thus, we are fully equipped to provide you with any services relating to

- Development
- Validation and Testing
- Approval process, including preparation of the technical documentation
- Manufacturing
- Packaging and sterilisation
- Quality assurance

of your device.

For further information regarding our own devices, please check out our website [www.medfact.eu](http://www.medfact.eu) or contact us directly via email using [office@medfact.eu](mailto:office@medfact.eu).