

MEDICAL TECHNOLOGY BUSINESS LOCATION GERMANY

OPPORTUNITIES FOR COMPANIES FROM CHINA

SINO-German Health Industry Weeks Roundup, Thursday, March 18th, 2021

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A large group of people, mostly in business attire, are posed for a group photo in a modern, spacious hall. The hall features a high ceiling with a complex glass and steel dome structure. Large, white, wing-like sculptures are suspended from the ceiling. The floor is covered with a red carpet. In the background, a large screen displays the text "GTAI-KONGRESS 2019". The overall atmosphere is professional and formal.

Germany Trade & Invest (GTAI) is the economic development agency of the Federal Republic of Germany.

Business Location Germany

- Market and industry analyses
- Market entry analyses
- Extensive legal information (tax, labor law, etc.)
- Funding and financing information
- Partnering and site selection support



Germany's medtech sector

Key figures

€36 bn

largest market in Europe

1300+

manufacturers (20+ empl.)

2/3

exports: „Made in Germany“ sells

1336

patent applications in 2018

€17 bn

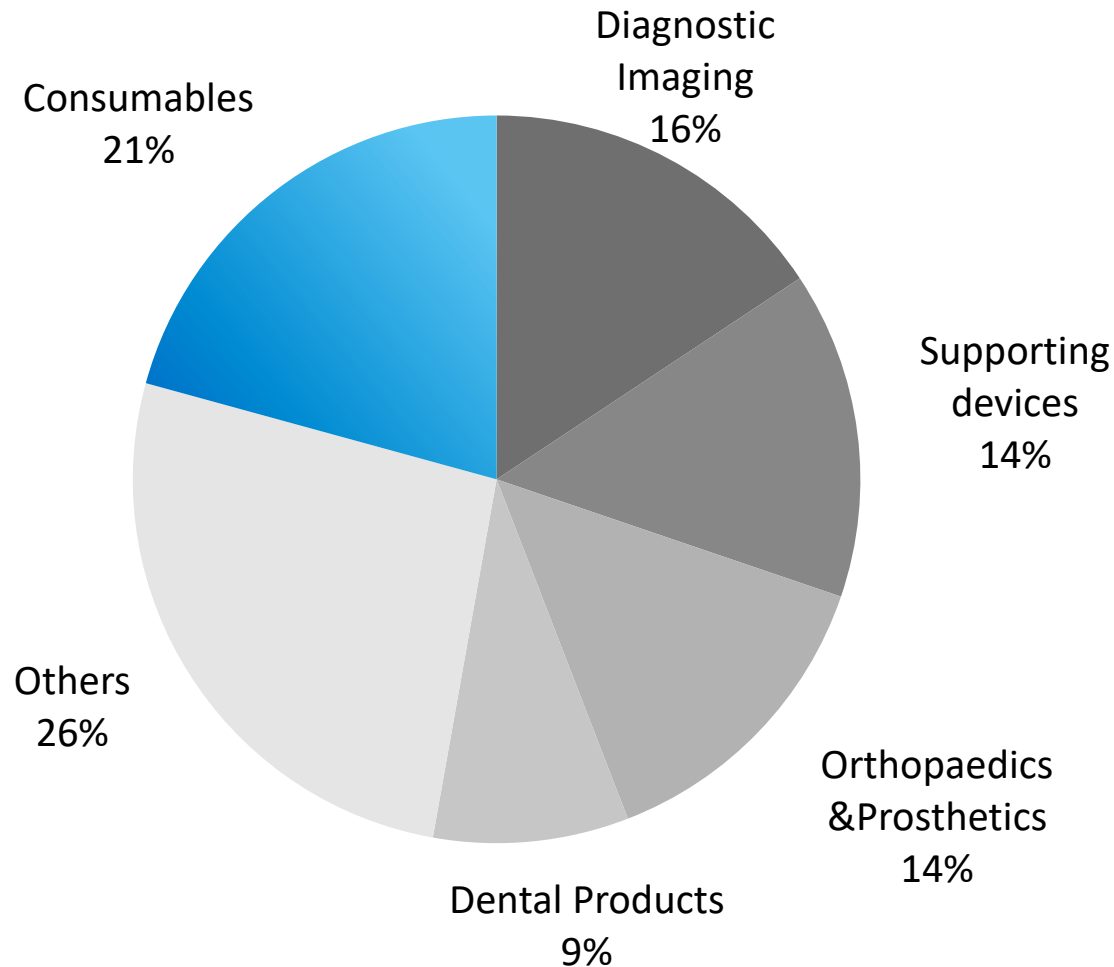
imports: high demand

CE

Medical Device Regulation (MDR)

Market Segments

Consumables is most important segment

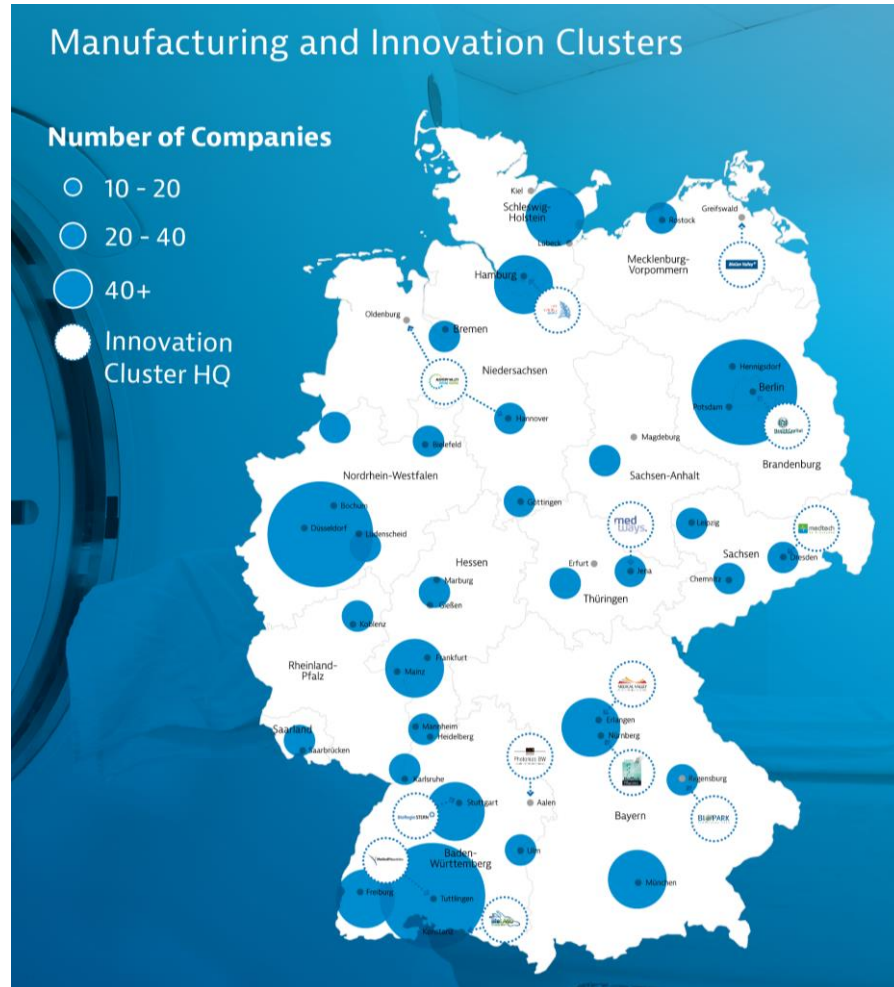


12,000 large medical apparatus are in use by hospitals

- **6,000 Dialysers**
- **1,500 MRI**
- **1,000 Coronary Angiographs**

Medtech Landscape

Production and innovation clusters accessible



**30+ innovation clusters
connecting industry
with academia, research
and clinical setting**

Germany's economic stimulus 2020

€ 130 bn

To cope with repercussions of COVID-19, maintain prosperity and increase future readiness

Healthcare sector share

€ 10 bn

To support hospitals, public health authorities, manufacturing and reserve of PPE, vaccines development



Market Access for Innovative Devices


CE certification: MDR to replace MDD


- Starting May 2021!
- Latest expiry of CE marks via MDD in 2025
- Notified bodies ready: BSI, TÜV Süd, Dekra
- EUDAMED is postponed

Market Access for Innovative Devices

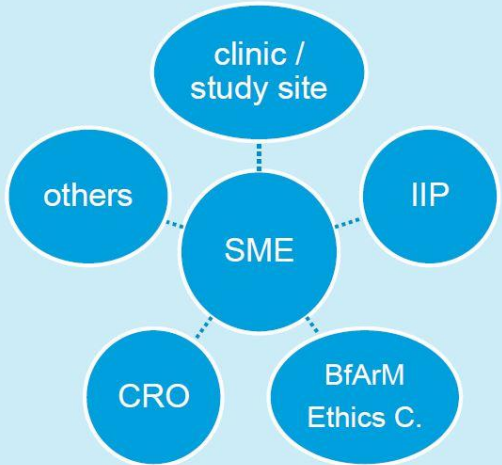
Clinical trials for CE (MDR) validation: Cash grants available

- For innovative class II/III
- Grant for training phase
- Grant for innovation phase
- Max. 70% of costs applicable

 **Technologiezentrum**

 BEAUFTRAGT VOM
**Bundesministerium
für Bildung
und Forschung**

Call for applications: Clinical evidence for medical devices



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graph TD; SME((SME)) --- clinic([clinic / study site]); SME --- IIP((IIP)); SME --- BfArM([BfArM Ethics C.]); SME --- CRO((CRO)); SME --- others([others]);
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Funding rate	Financing volume/(period)
<ul style="list-style-type: none">• Training aid: 50 % + boni• Innovation aid: 50 %	<ul style="list-style-type: none">• demand-oriented

Endpoints

- Modul 1: Application for clinical trial BfArM
- Modul 2: End of clinical trial

IIP: Industry in Clinic Plattform

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Market Access for Innovative Devices

Reimbursement in Germany

- In-patient sector: reimbursement unless product is on negative list (DRG System)
- Out-patient sector: reimbursement if product is put on positive list (national Focus on clinical evidence, limited HTA)
- Optional selective contracts with insurers

Potential Market Entry Modes Germany - R&D and Sourcing Centers

Advantages:

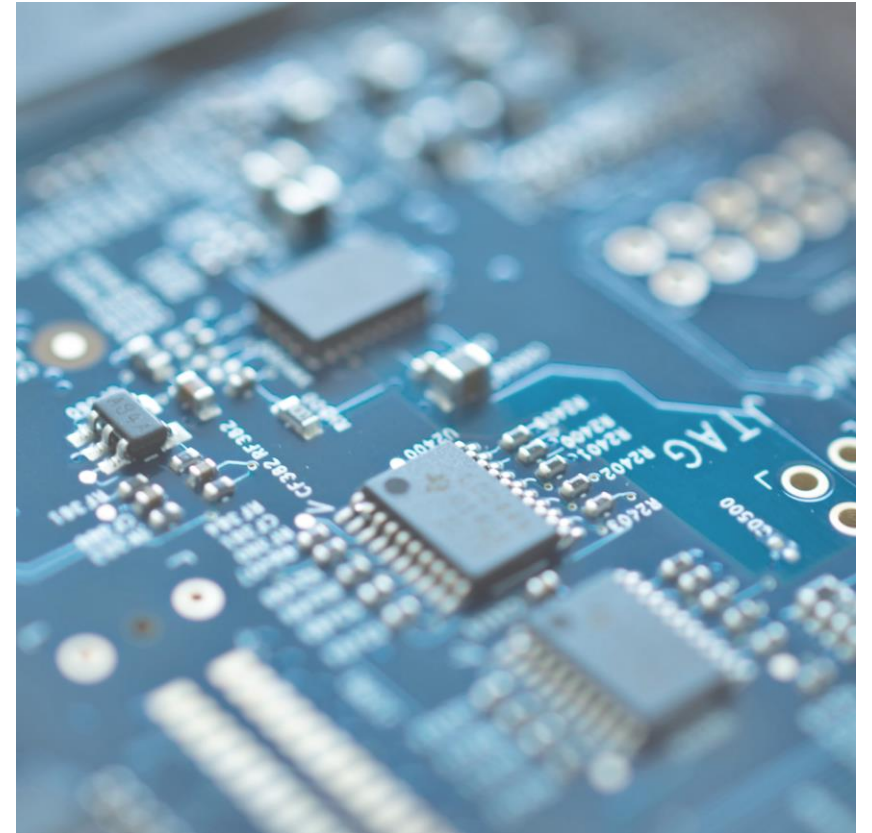
- Many strategic high-technology research collaboration partners accessible, e.g. Fraunhofer Institutes
- Advantageous Financing and Incentive opportunities available in Germany for Medtech companies
- Outstanding Research and Development partnering possibilities with innovation orientated suppliers in Germany



Potential Market Entry Modes Germany - High Value Manufacturing & Production

Advantages:

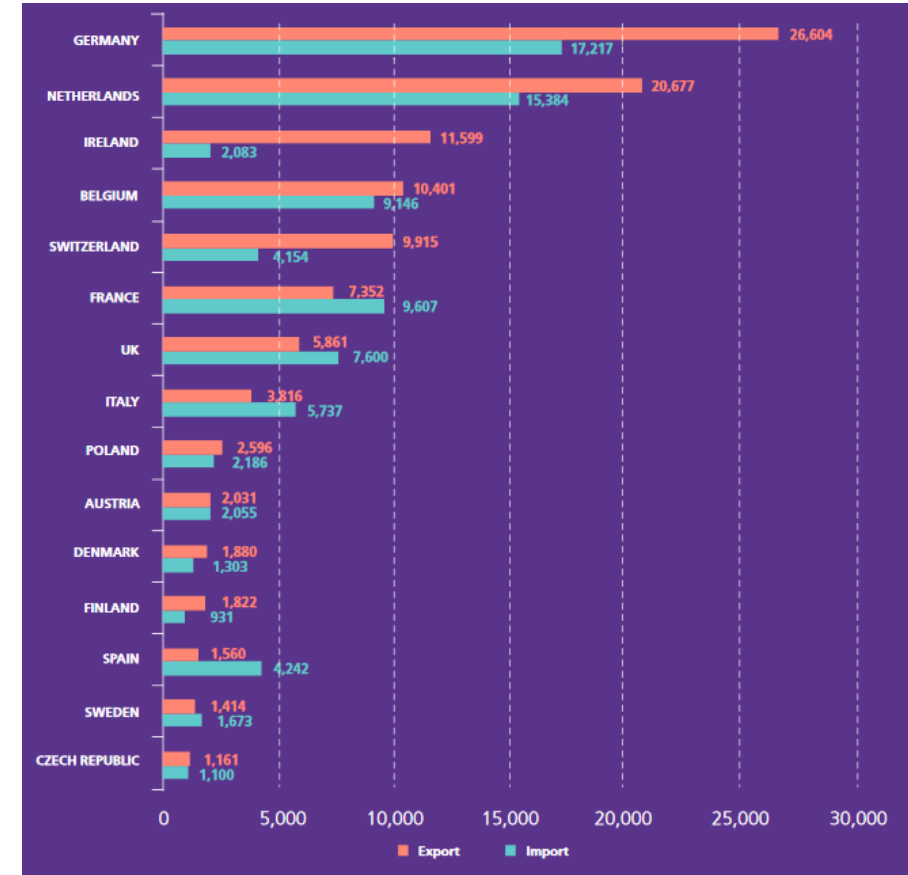
- Highly skilled and efficient workforce for medical technology manufacturing available
- „Made in Germany“ – branding
- Vast network of favorable policies and institutions that support medical device manufacturing
- Easy access to high-technology suppliers



European Union Medtech Landscape offers opportunities

Medtech Trade activity

- Germany is largest Trade Hub for Medtech in Europe
- The Netherlands second largest
- Ireland third largest



Source: Eucomed

Contact Us for further information

Germany Trade & Invest is the economic development agency of the Federal Republic of Germany. The company helps create and secure extra employment opportunities, strengthening Germany as a business location. With more than 50 offices in Germany and abroad and its network of partners throughout the world, Germany Trade & Invest supports German companies setting up in foreign markets, promotes Germany as a business location and assists foreign companies setting up in Germany.

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