GTAI GERMANY TRADE & INVEST

GERMANY'S MEDICAL DEVICE MARKET

How to Commercialize Innovative Medical Devices in Germany

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Gabriel Flemming, Senior Manager Chemicals & Healthcare, GTAI
Duncan Cunninghame, Business Development Manager - Europe & UK, The Insides Company

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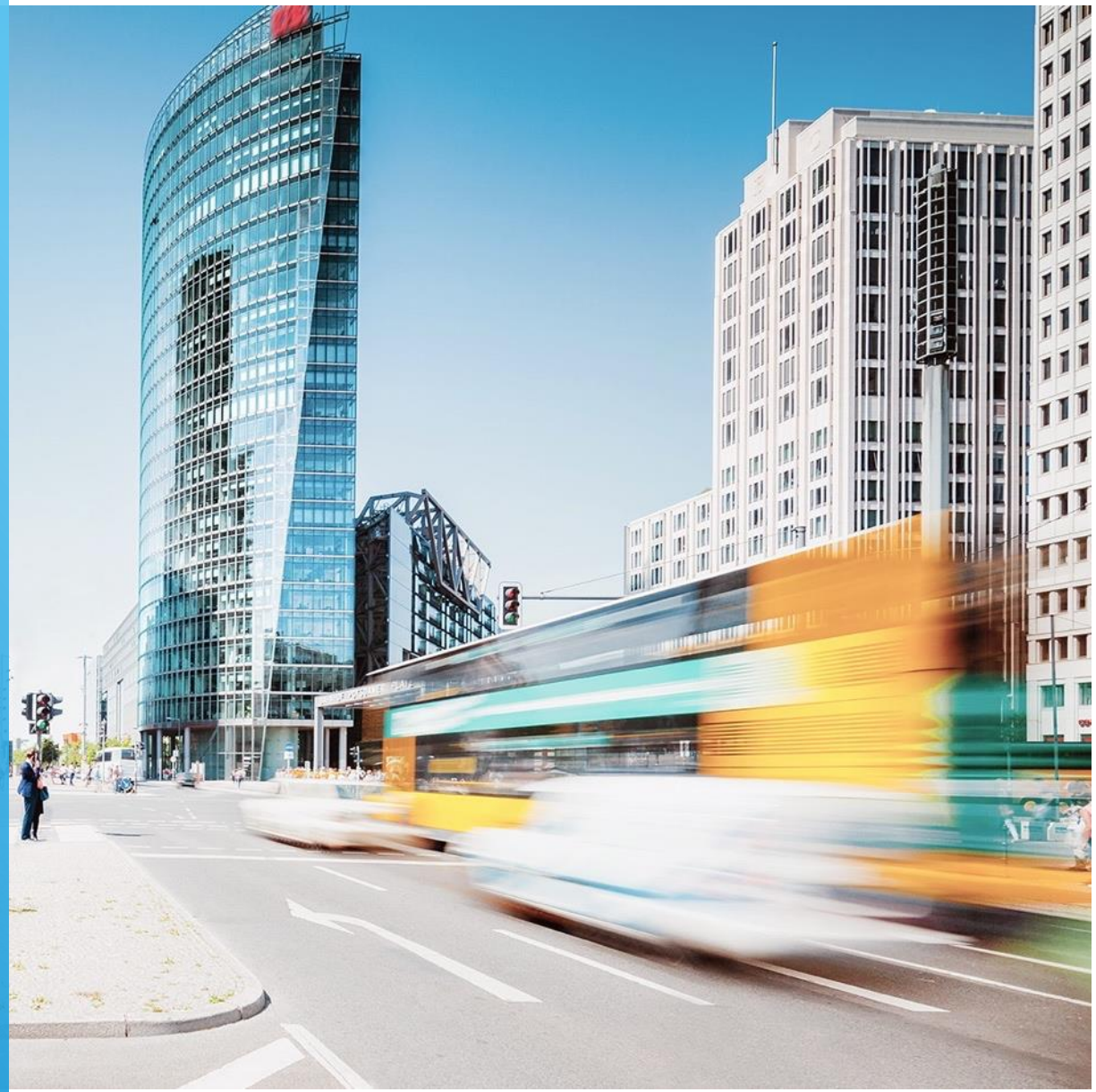
Germany Trade & Invest (GTAI) is the economic development agency of the Federal Republic of Germany.

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



Healthcare Market Germany

€ 400 billion
healthcare expenditure

11.7%
of GDP

73 million
people have public health insurance

9 million
people privately insured

1925
hospitals

500k
beds

385,000
physicians

20,000
pharmacies

7.5 million
employment in healthcare

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

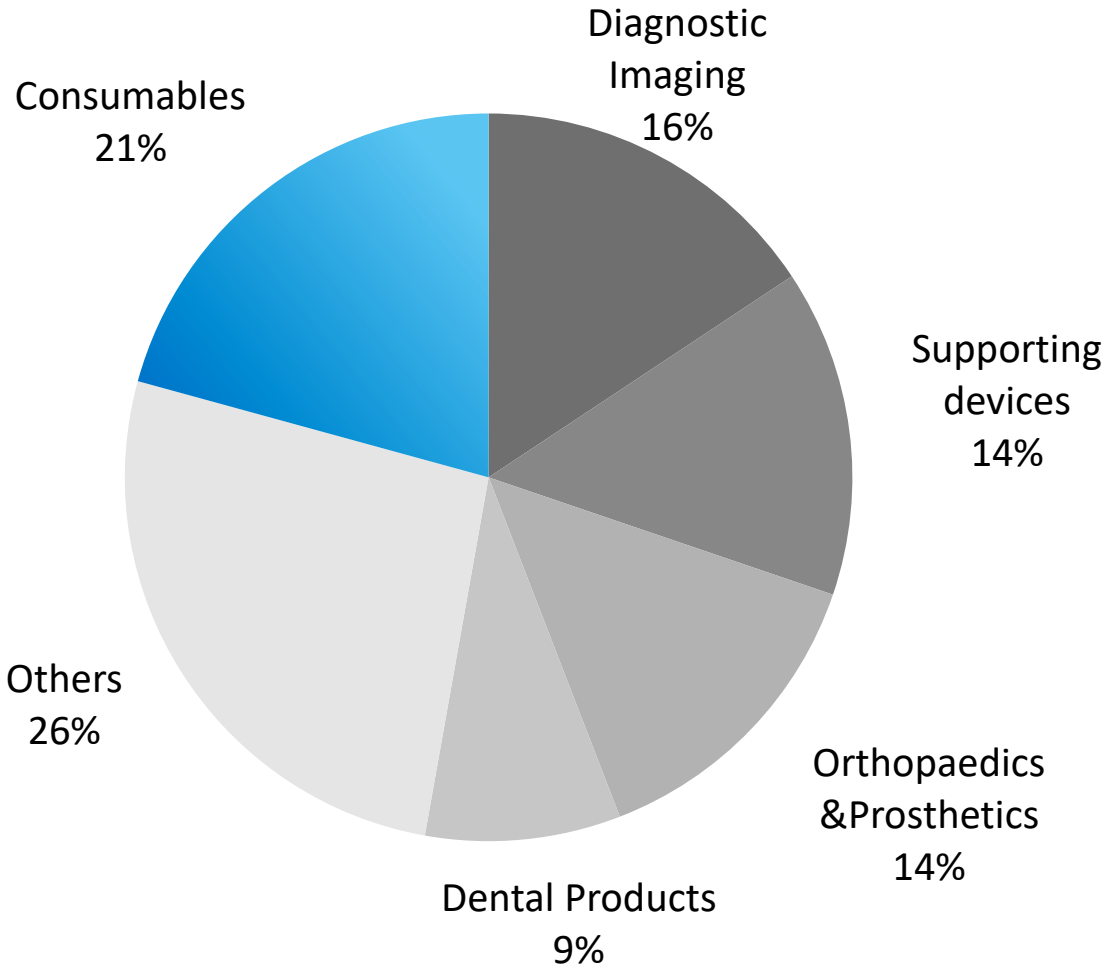
€17 bn
imports: high demand

CE
Medical Device Regulation (MDR)

Source: BVMed, Statista

Market Segments

Consumables is most important segment



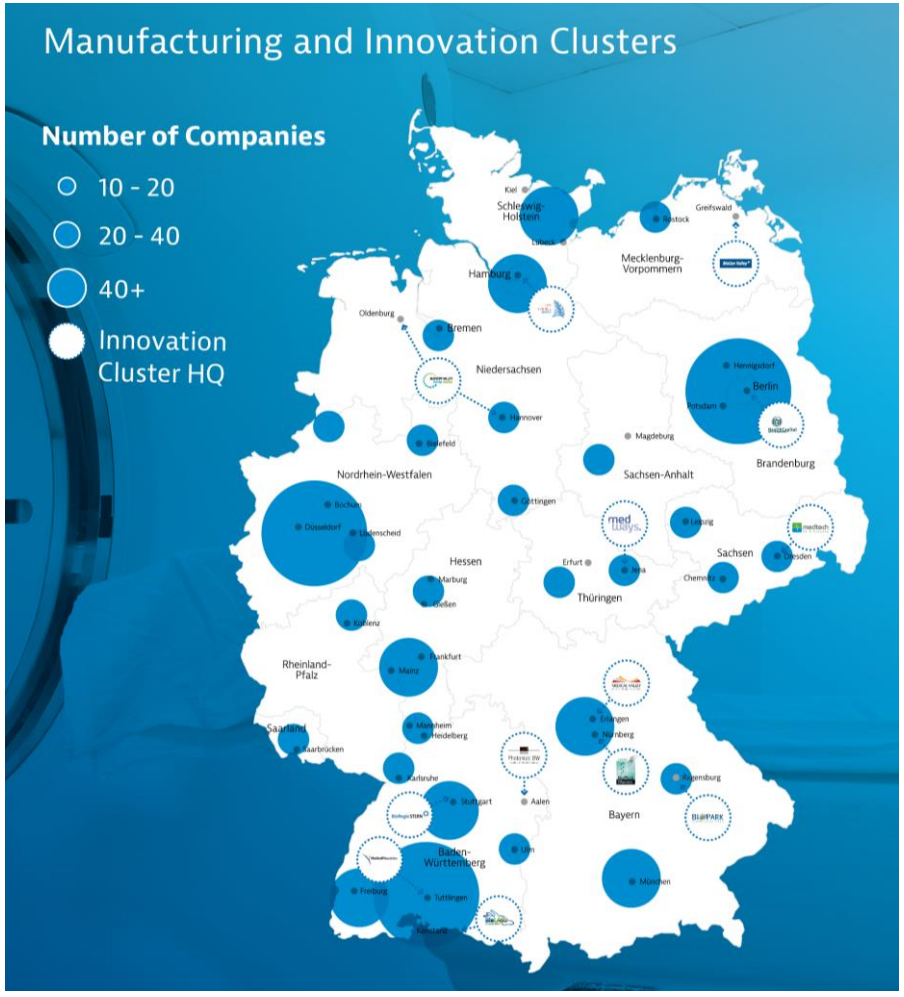
12,000 large medical apparatus are in use by hospitals

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

Source: FitchSolutions Medical Devices Report 2019

Medtech Landscape

Production and innovation clusters accessible



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

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

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

Market Access for Innovative Devices

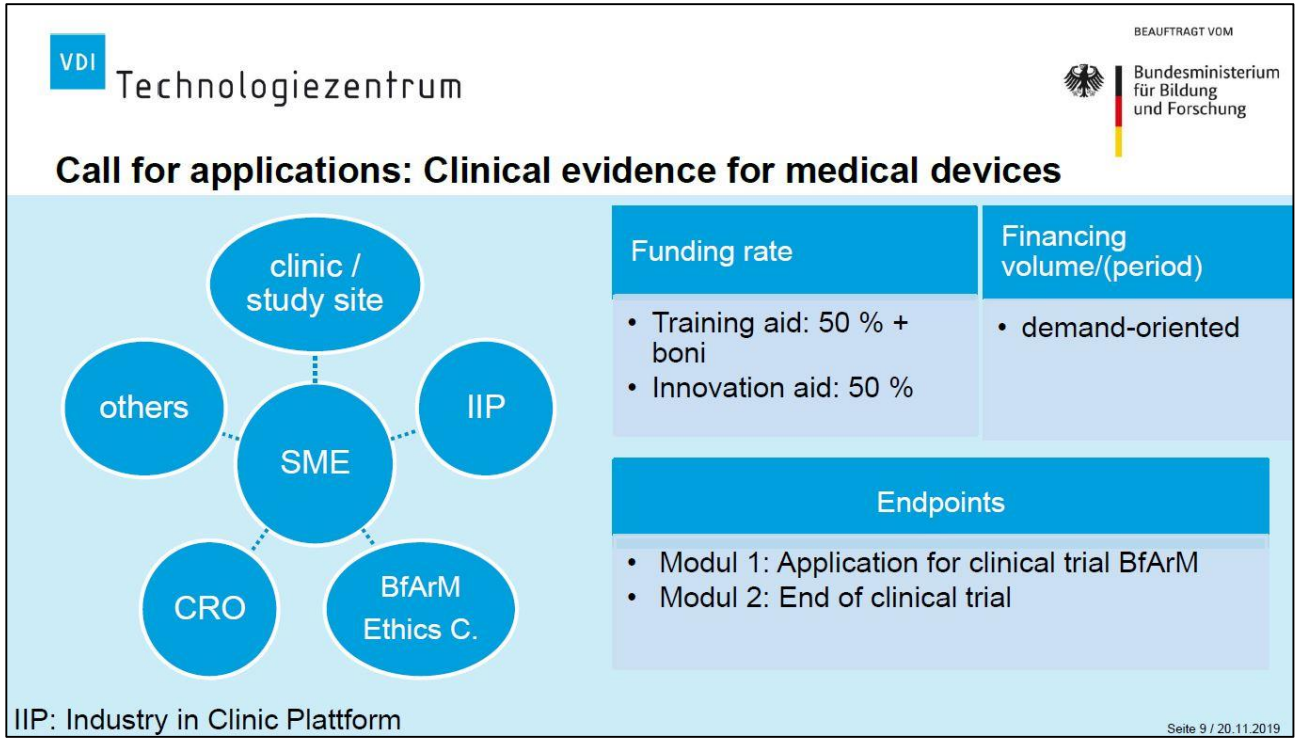
Clinical trials for CE and reimbursement

MDR: Class IIb+III →	New CE requires more individual clinical data. Equivalence via literature is limited
Reimbursement: Coverage by evidence →	Preliminary reimbursement is granted in ongoing clinical trials
Reimbursement: New class III methods require RCT →	„HTA“ dossier provided by hospital and manufacturer, clinical trial completed

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



Source: VDI Technologiezentrum

Contact Us

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.

Contact
Gabriel Flemming
T +49 (0)30 200 099-307
Gabriel.flemming@gtai.com

Berlin
Friedrichstraße 60
10117 Berlin
www.gtai.com

Bonn
Villemombler Straße 76
53123 Bonn
www.gtai.de

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