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# „Succeed in Germany's Healthcare Market: Understand the Market and the Medical Device Industry"

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GTAI Webinar Series Succeed in Germany's Healthcare Market  
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**GERMANY  
TRADE & INVEST**

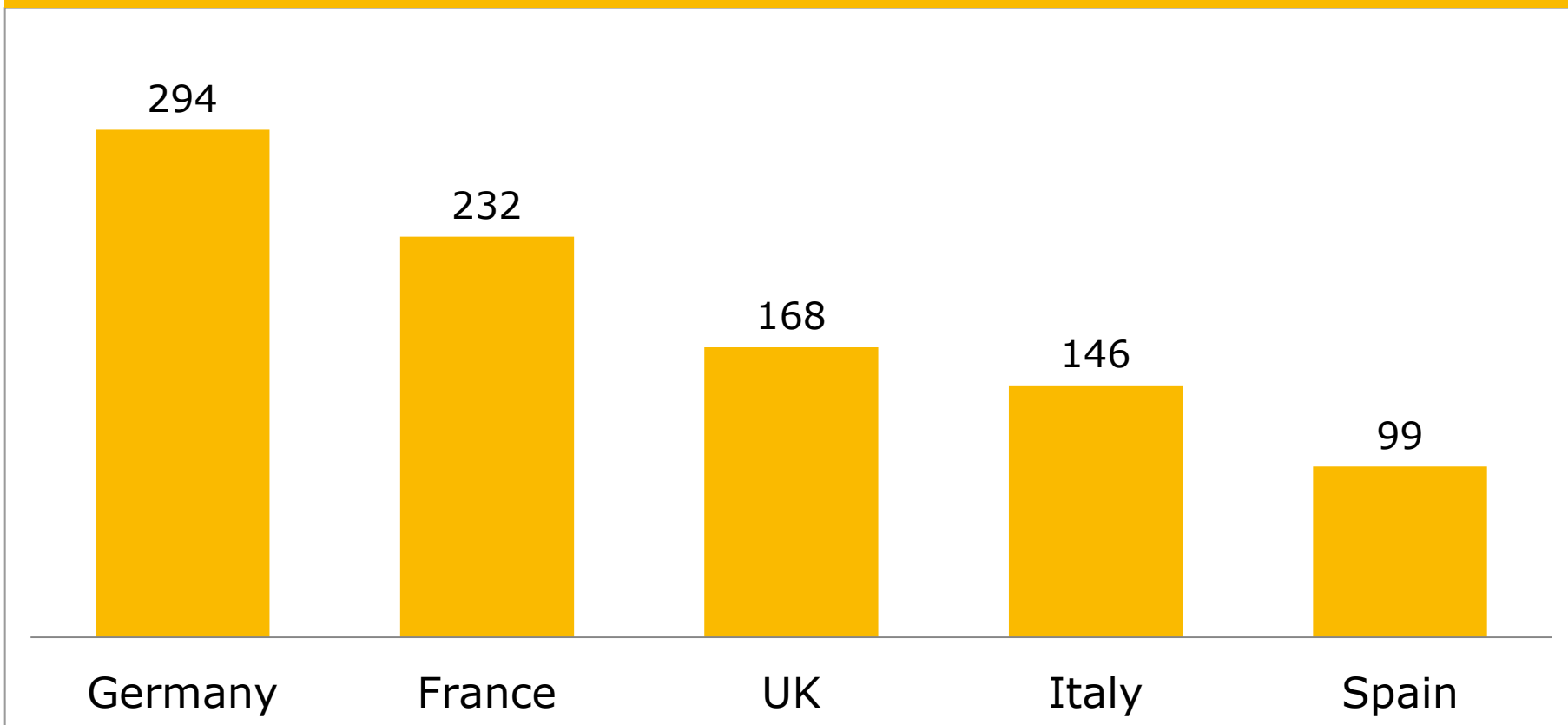
I. The German Healthcare System: Market Demand

II. The German Market for Medical Devices

III. Contacts

Health care expenses totaled 294bn€ with a 2% increase to 2010

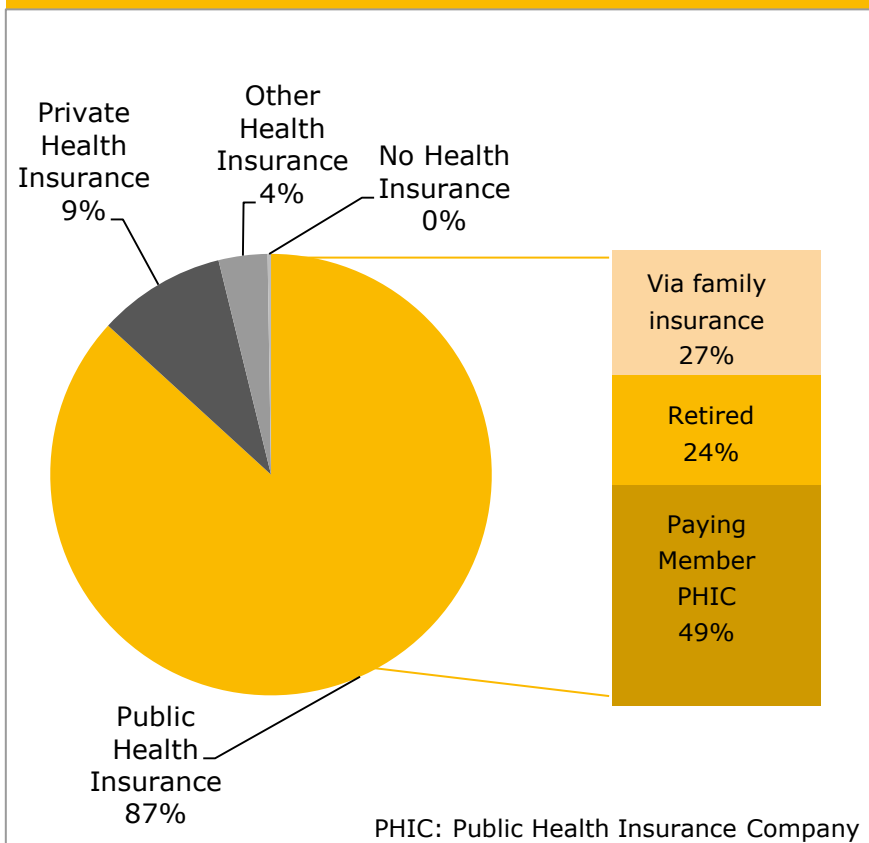
## Total Annual Health Expenditure in 2011 (€ bn)



Source: OECD 2013

## Healthcare spending in Germany accounts for 11.6% of GDP

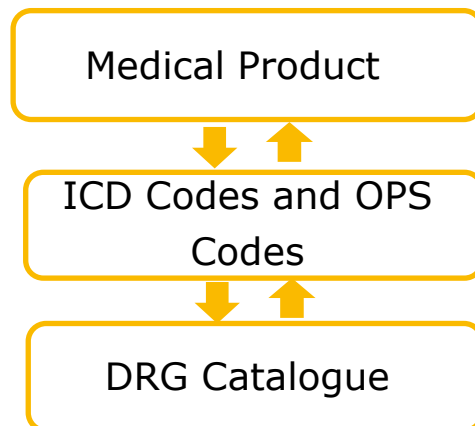
### Germany's Population - Health Insurance Status (2012)



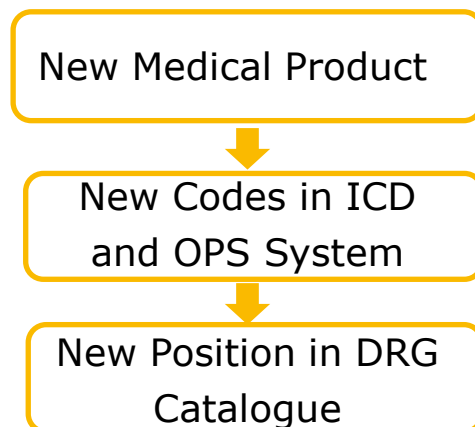
- German population 82 million people
- About 70 million people in Germany have public health insurance
- 134 public health insurance companies with € 173 bn healthcare € 30 bn accumulated surplus
- Healthcare spending of private health insurance companies – €22,7 bn (2011)
- 33% spent on hospital treatment
- There are 2045 hospitals with 502.749 beds in Germany (2011)

Source: DESTATIS: Grunddaten der Krankenhäuser 2013; BV MED – Branchenbericht 2013

## The German In-patient market: Hospitals and the DRG system



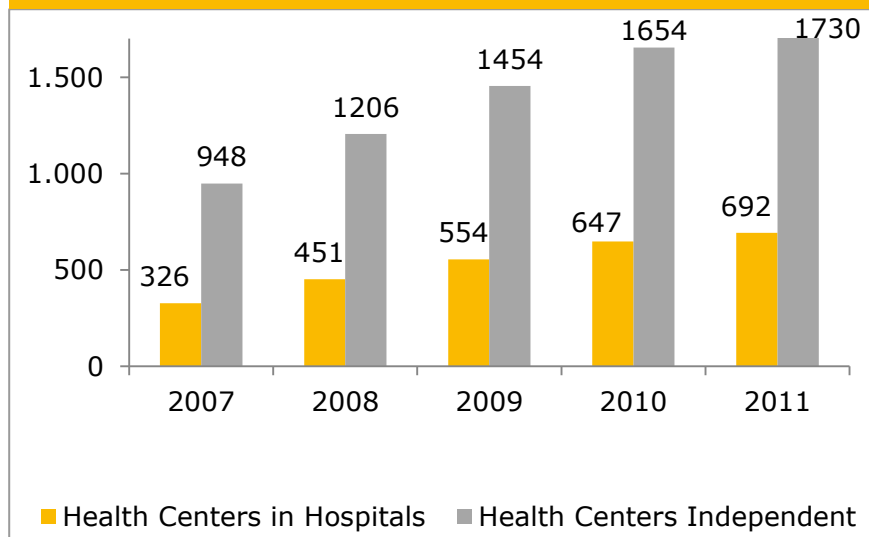
### If no codes apply: NUB process



- Diagnose Related Groups System (G-DRG) for reimbursement between hospitals and insurances: approx. 1200 individual flat-rates in DRG catalogue
- Flat-rate compensation according to (ICPM) International Classification of Procedures in Medicine:
  - Diagnoses: ICD Coding System
  - Procedures: OPS Coding System
- Transparency provided via public catalogue of flat-rates published by „INeK“-Institute for the hospital remuneration system: numbers of procedures, age groups, flat-rate sum

## Ambulant and Out-Patient Sector

### Development of Health Centers in Germany (2007 – 2011)



- 2422 health centers in Germany
- 342,000 active medical doctors
- 142,900 medical doctors in the outpatient sector
- 102,000 medical practices (2011)

### Uniform Valuation Standard (EBM):

- The EBM defines the shape and scope of Physician Services and defines the corresponding prices in Euro.
- Physician Services can consist of Medical Products or technologies, surgical dressings, general appliances:
- Medical Products may also be included in Catalogue of Medical Appliances and its Appendix for Care Appliances.
- Costs are covered by insurance in case of physician's prescription.

Source: Kassenärztliche Bundesvereinigung 2011; Statistik der Bundesärztekammer; Gesundheitsberichterstattung des Bundes

## Definition of Medical Devices/Medical Products:

all products e.g. instruments, apparatus, materials, software or other items that are designed for diagnosis, prevention, surveillance, treatment or compensation of human illnesses, injuries or handicap

### Class I

- Medical instruments
- Crutches
- Wheel chair
- Beds
- Bandaging

### Class IIa

- Dental filler
- Diagnostic ultrasonic devices
- Hearing aids
- Contact lenses
- Tooth crowns
- Muscle and nerve stimulation

### Class IIb

- Anesthetic devices
- Respiration devices
- X-ray
- Blood bags
- Defibrillator
- Dialysis devices
- Contact lense cleaner
- Dental implants

### Class III

- Heart catheter
- Endoprothesis
- Coronary stents
- Absorbable surgical suture
- Heart valves

Please note that neither EU-rules nor national legislation carry out such a classification of medical devices because, in each particular case, a classification has to be conducted with reference to the intended use; *Source: MED Cert*

## CE-Mark for medical devices

### CE-Certification Process

The CE-Certification system is detached from public authorities, which are not involved directly

- Depending on the risk classification (I, IIa, IIb, III) a notified body e.g. TÜV, DEKRA must be approached, which will perform the conformity assessment procedure and will provide the CE-Mark: product safety, fulfillment of advertised product function, surveillance of manufacturer and product must be provided

### Cost and Time to market

- The European CE-certification process is not significantly quicker than the US 510(k) FDA.
- Time-to-market for innovative products (PMA) is similar in case of reimbursement procedures
- Clinical expenses are significantly lower
- Cost of CE certification ranging on average between 7.000 – 80.000 EUR



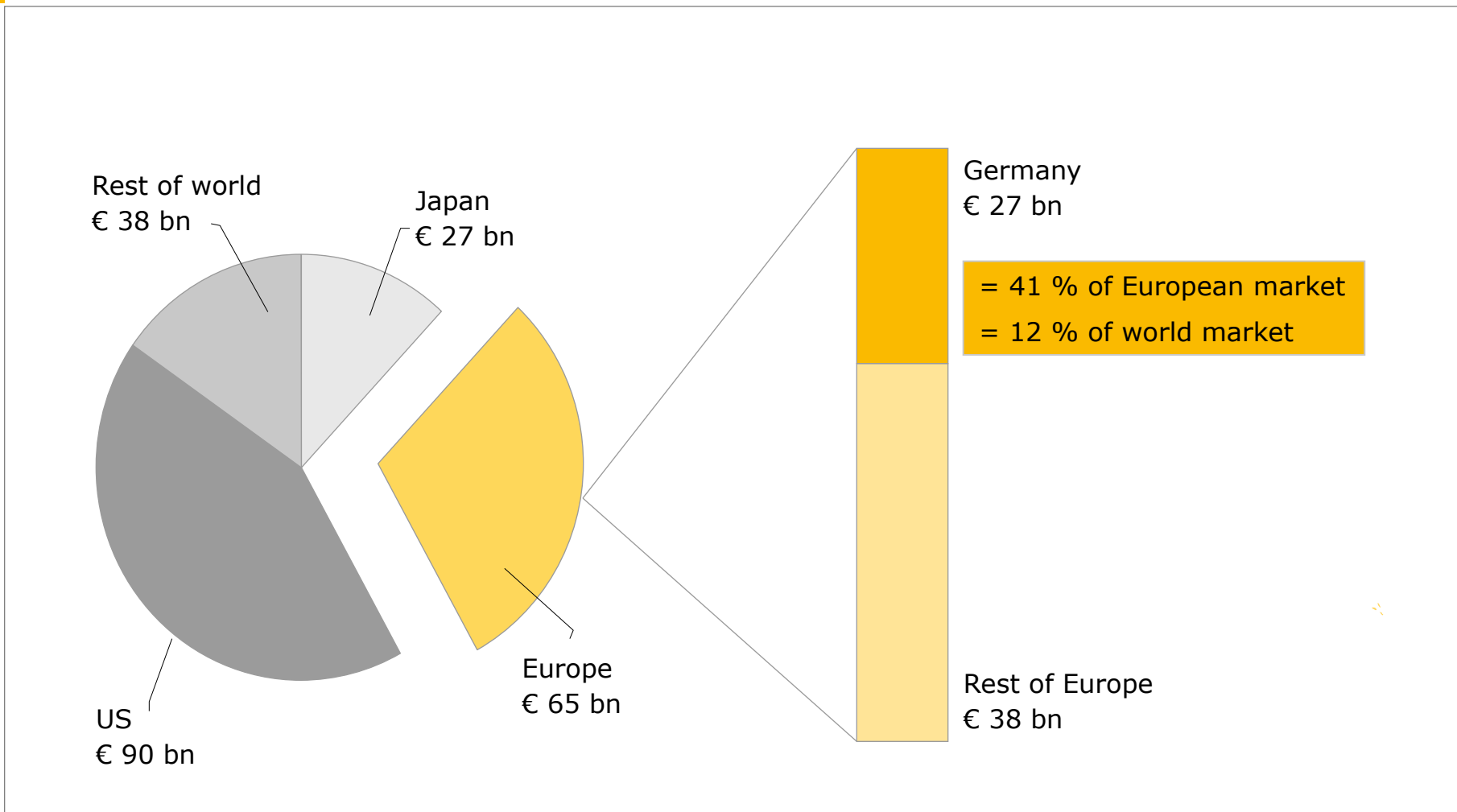


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## Worldwide Market for Medical Devices: € 220 billion



Source: BvMed Annual Report 2013

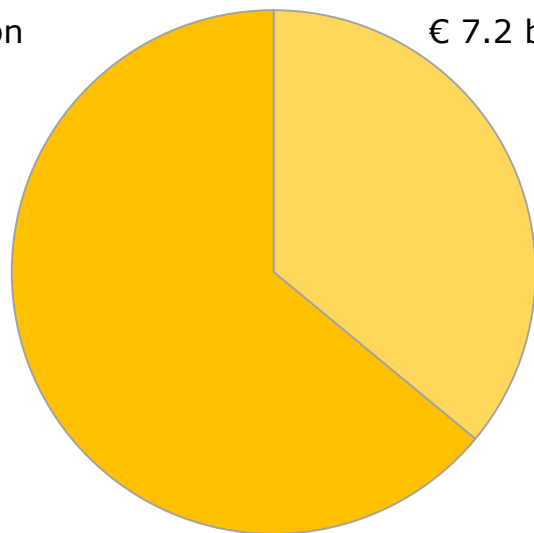
The medical device industry contributes significantly to the German healthcare industry

## Total production volume:

€ 22.2 billion (+6,9%)

Export  
67.0%  
€ 15 bn

Domestic sales  
33.0 %  
€ 7.2 bn



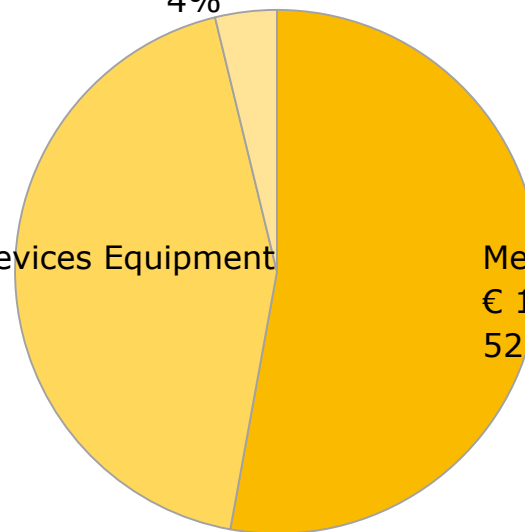
## Total expenditures on medical devices: € 27 billion

€ 27 billion

Dressings  
€ 1 bn  
4%

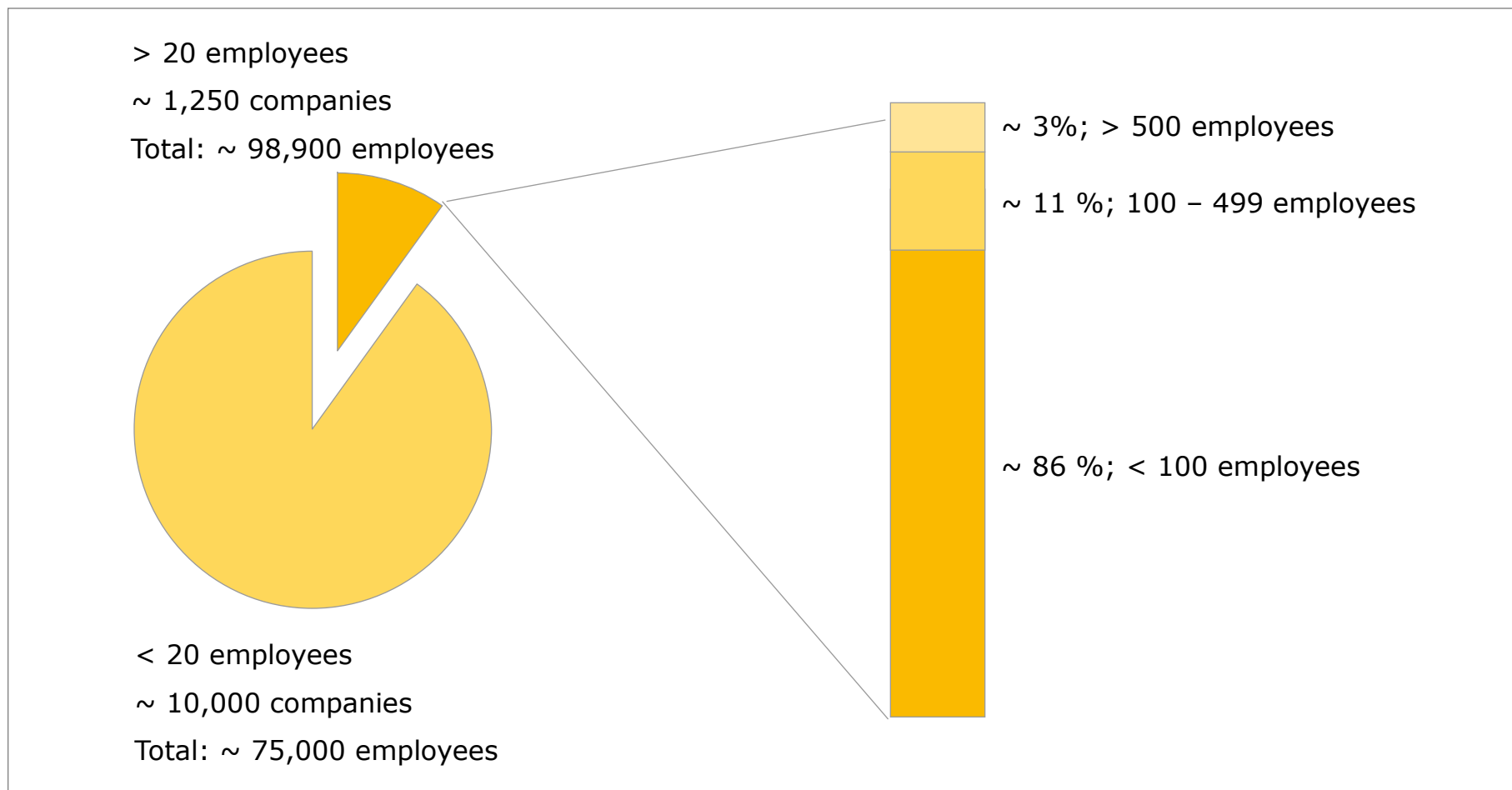
Medical Devices Equipment  
€ 12 bn  
44%

Medical Aids  
€ 14 bn  
52%



Source: BvMed Annual Report 2013

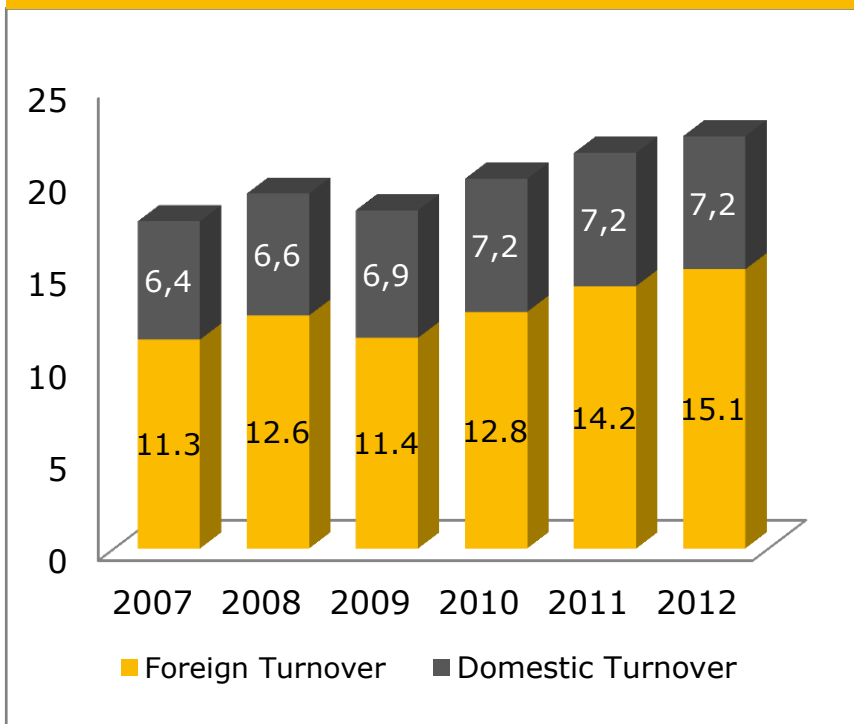
About 175,000 people work in Germany's medical device industry in over 11,000 companies (excl. Retail)



Source: BVMed Annual Report 2013

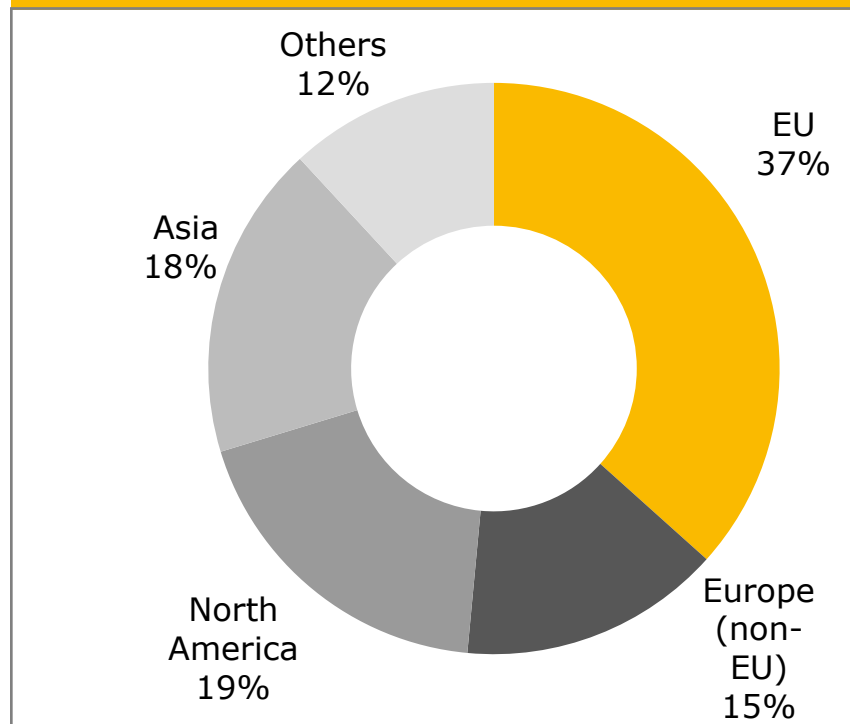
## Growing exports beyond Europe

### Development of external sales of medical devices (in € bn)



Source: Spectaris 2013

### Destination countries of medical device exports (2013)



Source: SPECTARIS 2013

## The Top 10 medical technology manufacturers in Germany

	<b>Company</b>	<b>Sales € (mln)</b>	<b>Number of Employees</b>	<b>Products</b>
1	Fresenius	15,972	145,118	diverse medical devices/pharmaceuticals
2	Siemens Medical	8,686	8,000	imaging/laboratory diagnostics
3	Drägerwerk	2,177	11,825	diverse diagnostic devices
4	Paul Hartmann AG	1,687	10,045	medical appliances and dressings
5	Karl Storz GmbH	866,261	5,300	diverse products
6	Carl Zeiss Meditech AG	758,793	2,366	diverse diagnostic devices
7	Aesculap AG	550,206	3,000	operational and interventional devices and systems
8	Otto Bock Healthcare	500,000	4,361	medical aids, prostheses and implants
9	Biotronik	452,800	5,600	pacemakers
10	MEC Holding GmbH	448,442	2,400	medical/laboratory diagnostic devices

Source: [www.onesource.com](http://www.onesource.com)

## Related industries provide additional opportunities for US companies

### **Machinery and Equipment Industry**

- € 170 bn turnover (2012)
- strongest in Europe
- 6.300 companies along the value chain

### **Electronics and Microtechnology**

- € 180 bn and 82 bn turnover (2012)
- More than 1 mln jobs
- highly innovative (€ 12 bn R&D in 2012)

## **Medical Technology**

Turnover: € 27 bn

### **Photonics and Consumer Optics**

- € 27 bn production, 66% exports
- 1000 companies, 134,000 employees
- Consumer Optics: € 3.95 bn turnover
- € 1.95 bn external sales
- 150 companies, 21,300 employees

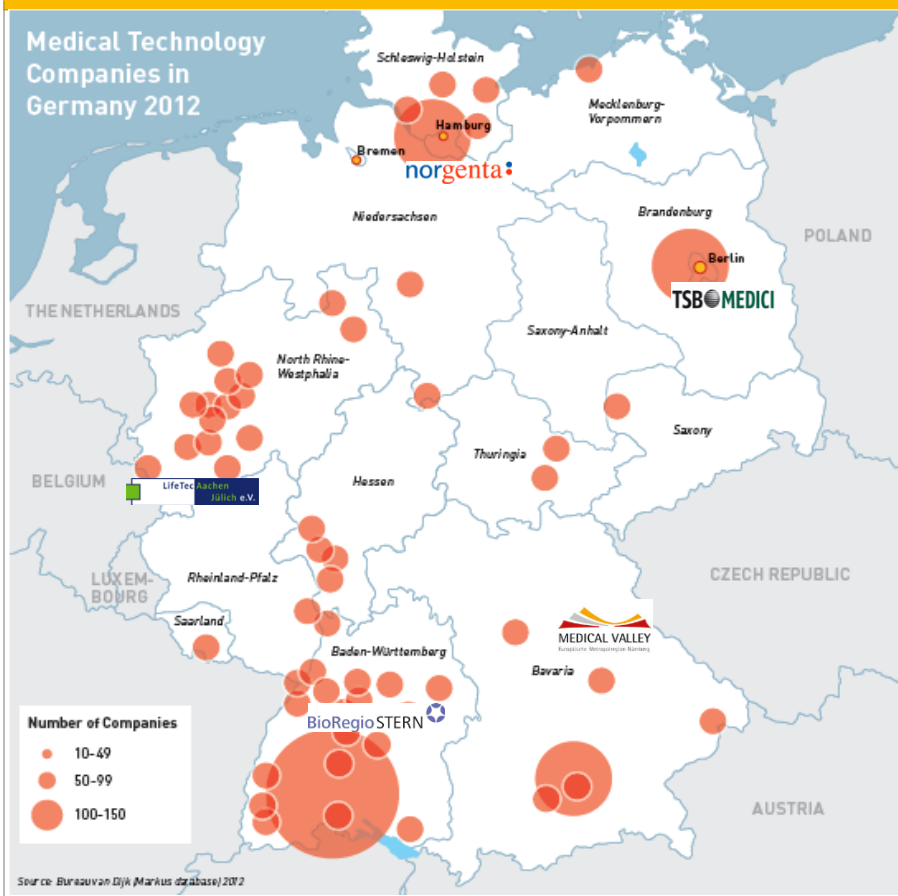
### **Electromedical Industry**

- € 8,9 bn turnover (2011)
- Trends:
  - Minimally invasive treatments
  - Home-use devices
  - Digital medical imaging

Source: Germany Trade & Invest; SPECTARIS

Industry clusters are spread throughout the country - examples

## Medical Technology Clusters and Companies in Germany



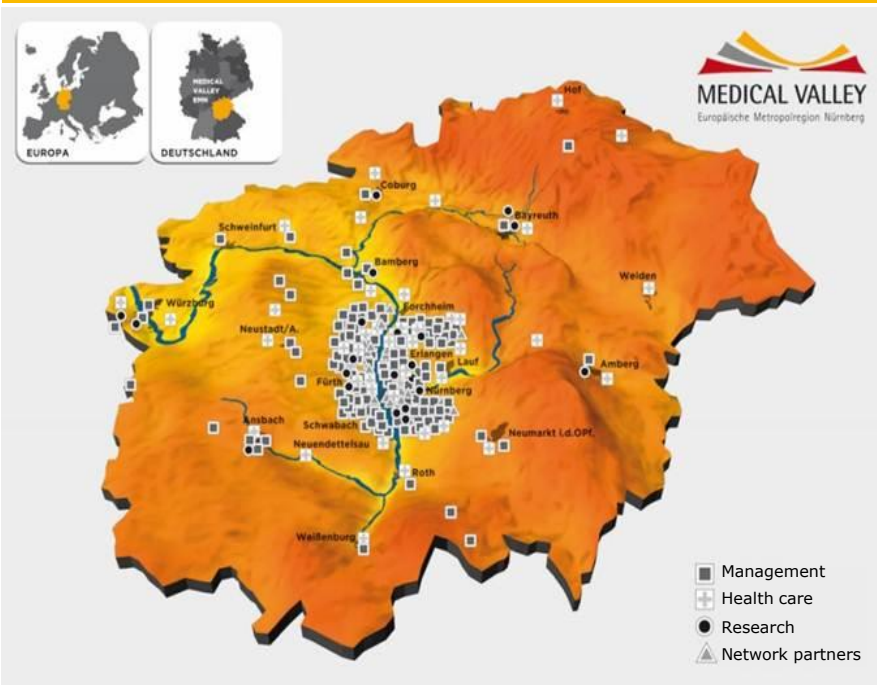
Relevant associations in Germany:

- **BVMed Bundesverband Medizintechnologie e.V.** (Federal Association of the Medical Device Industry) represents more than 230 medical technology companies
- **SPECTARIS** - association of the high-tech industries in Germany
- **ZVEI Zentralverband Elektrotechnik und Elektroindustrie e.V.** - association of the German electronics industry



## Exemplary Cluster Profile – Medical Valley EMN

### The National Leading Edge Cluster Medical Valley Nuremberg



- Medical Valley EMN is one of Germany's Leading Edge Clusters
- Over 180 dedicated medical engineering companies
- Projects worth about 80 million Euro will be realized until 2015
- Main project topics include:
  - Medical imaging
  - Intelligent sensor technology
  - Therapeutic systems
  - Ophthalmology
  - Horizontal innovations for product and process optimizations

# Germany Trade & Invest

## Contact

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