

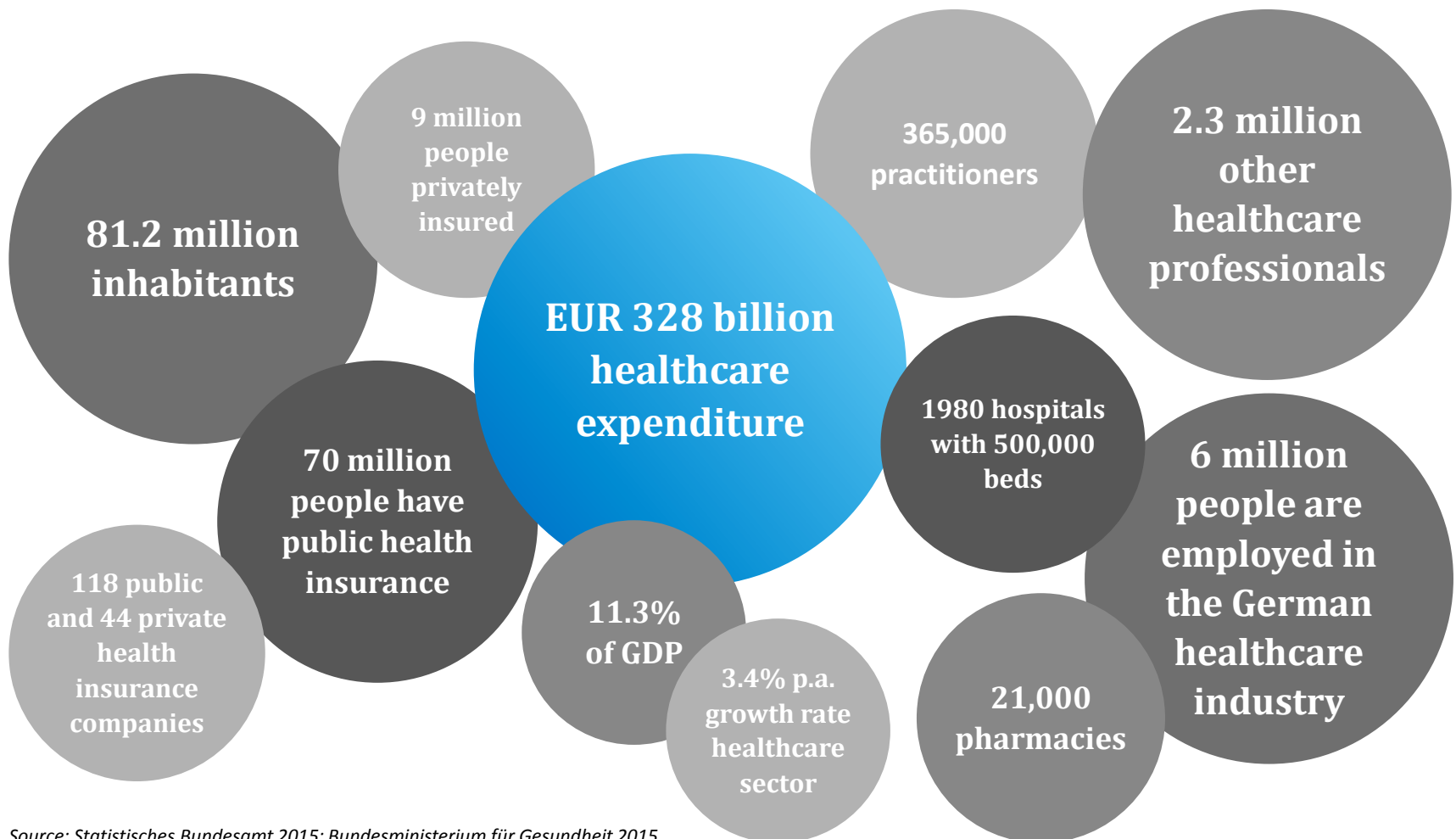
CURRENT TRENDS AND OPPORTUNITIES IN GERMANY'S HEALTH MARKETS

12TH JAPAN-GERMANY INDUSTRY FORUM,
TOKYO, DEC 1, 2016

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Healthcare in Germany

One of Germany's largest growth markets at a glance

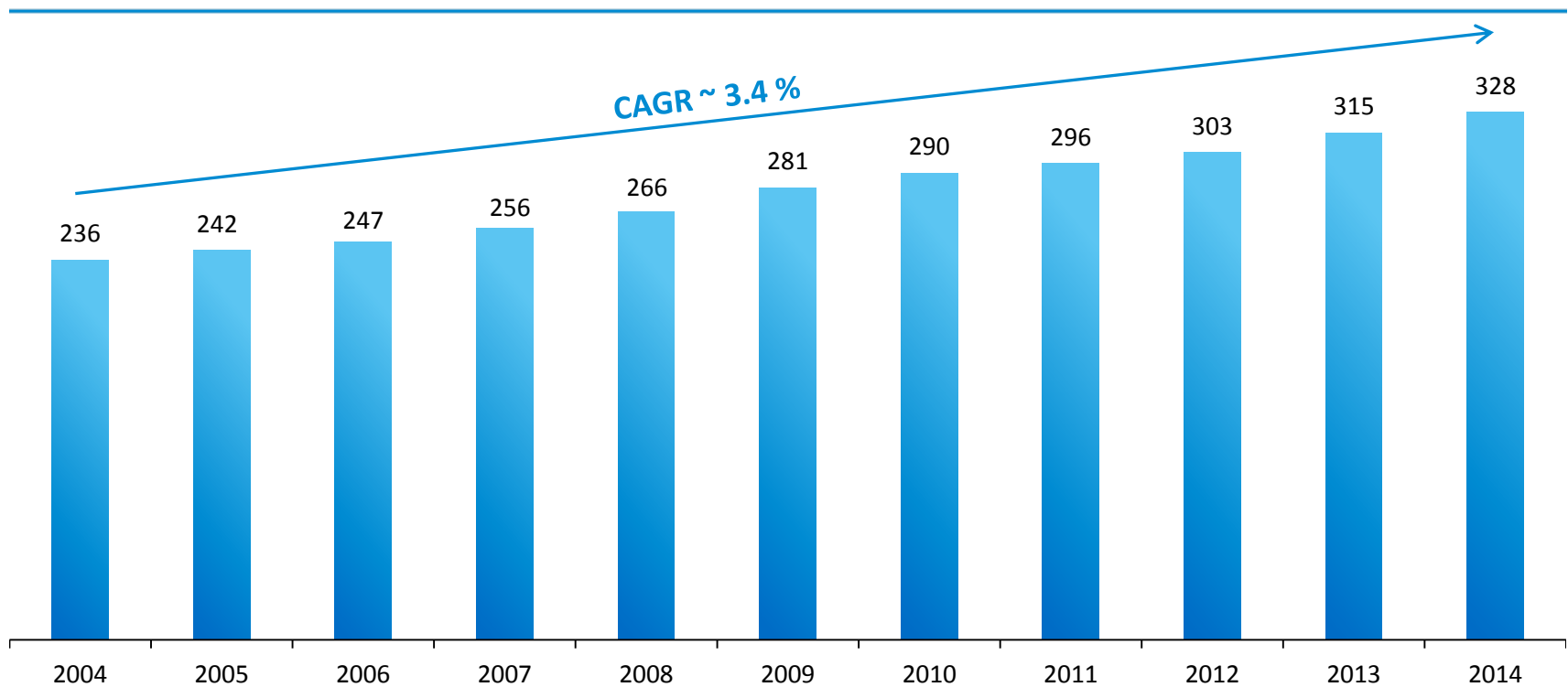


Source: Statistisches Bundesamt 2015; Bundesministerium für Gesundheit 2015

Germany's health markets

Healthcare expenditure in Germany exceeded the EUR 300 billion mark

Healthcare expenditure in Germany 2004 - 2014 (in EUR billion)

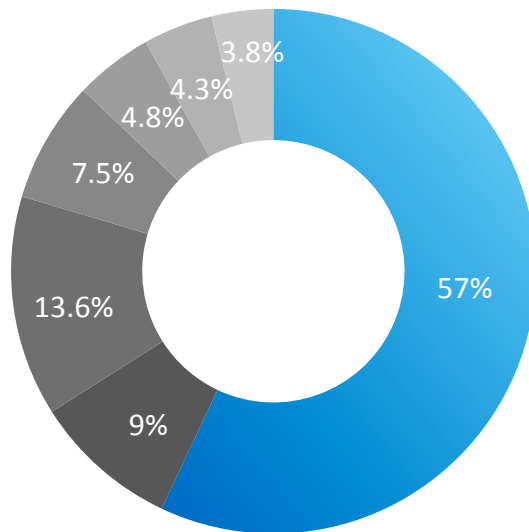


Source: Statistisches Bundesamt 2015

Germany's health markets

In-patient and out-patient sector spending

Who covers health care cost in Germany?

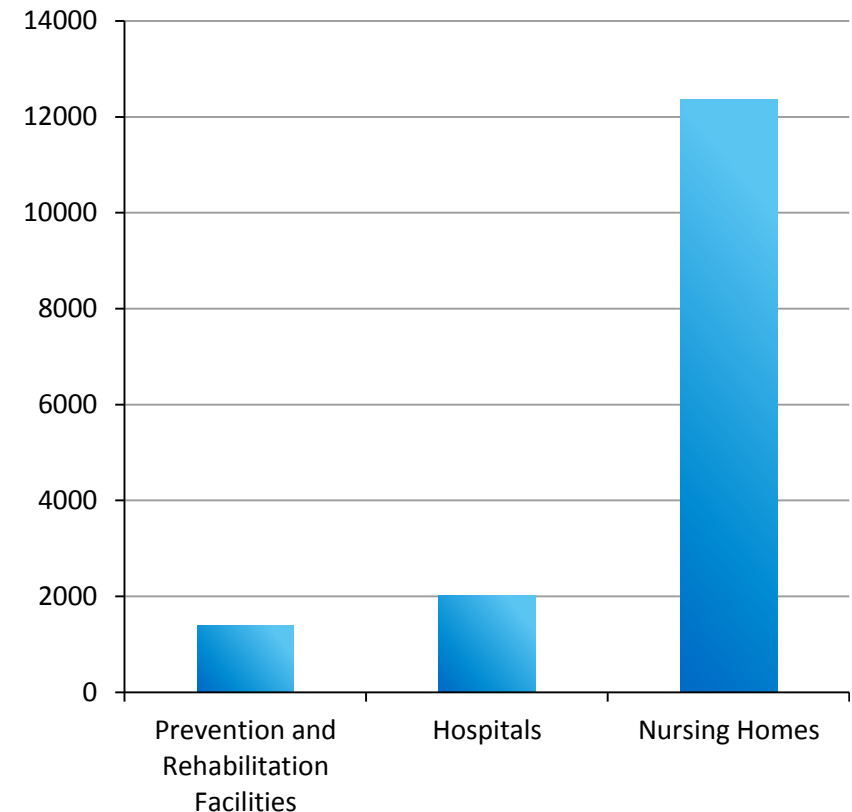


- Public Health Insurance
- Private Health Insurance
- Private Households
- Nursing Care Insurance
- Administration Health
- Employers
- Retirement and Accident Insurance

Source: DKG, Spectaris, Gesundheitsberichterstattung des Bundes

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Number of Hospitals and Care Centers

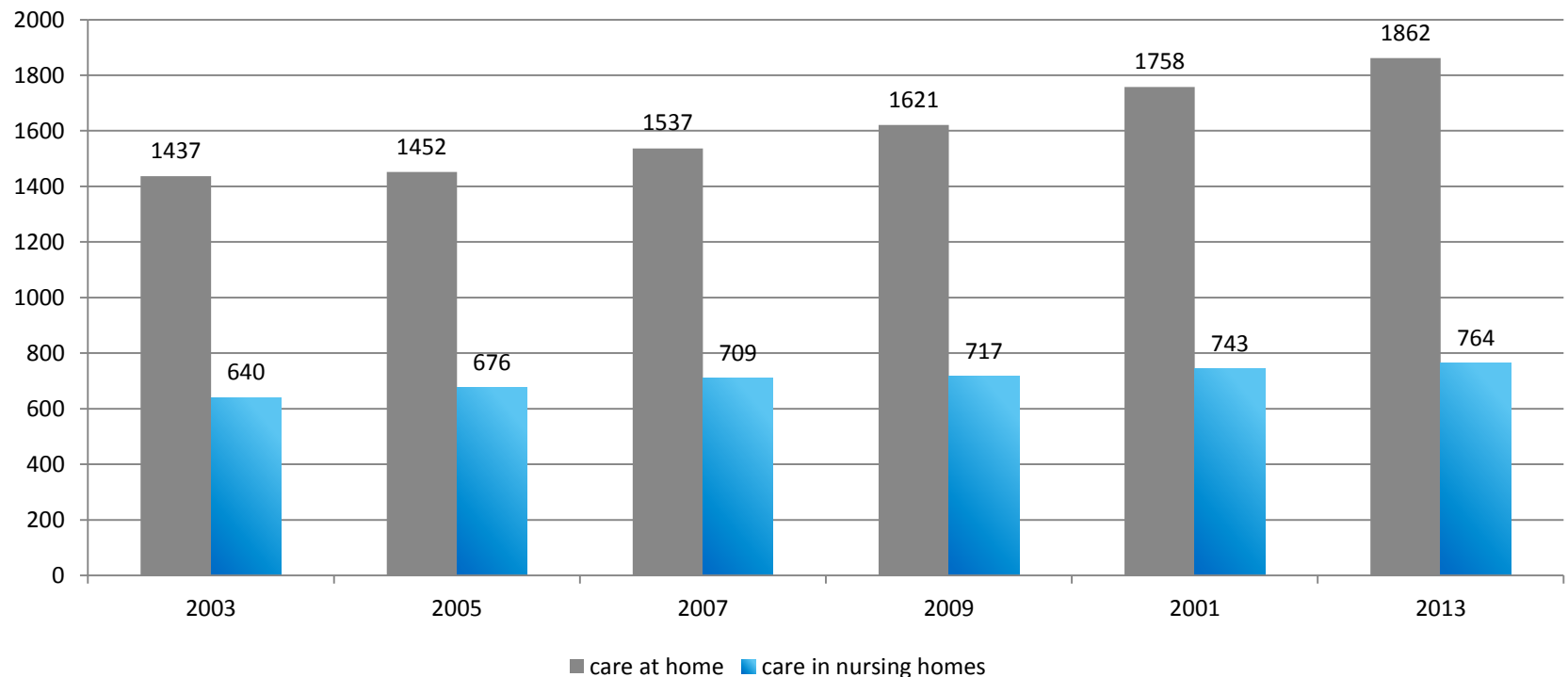


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Germany's health markets

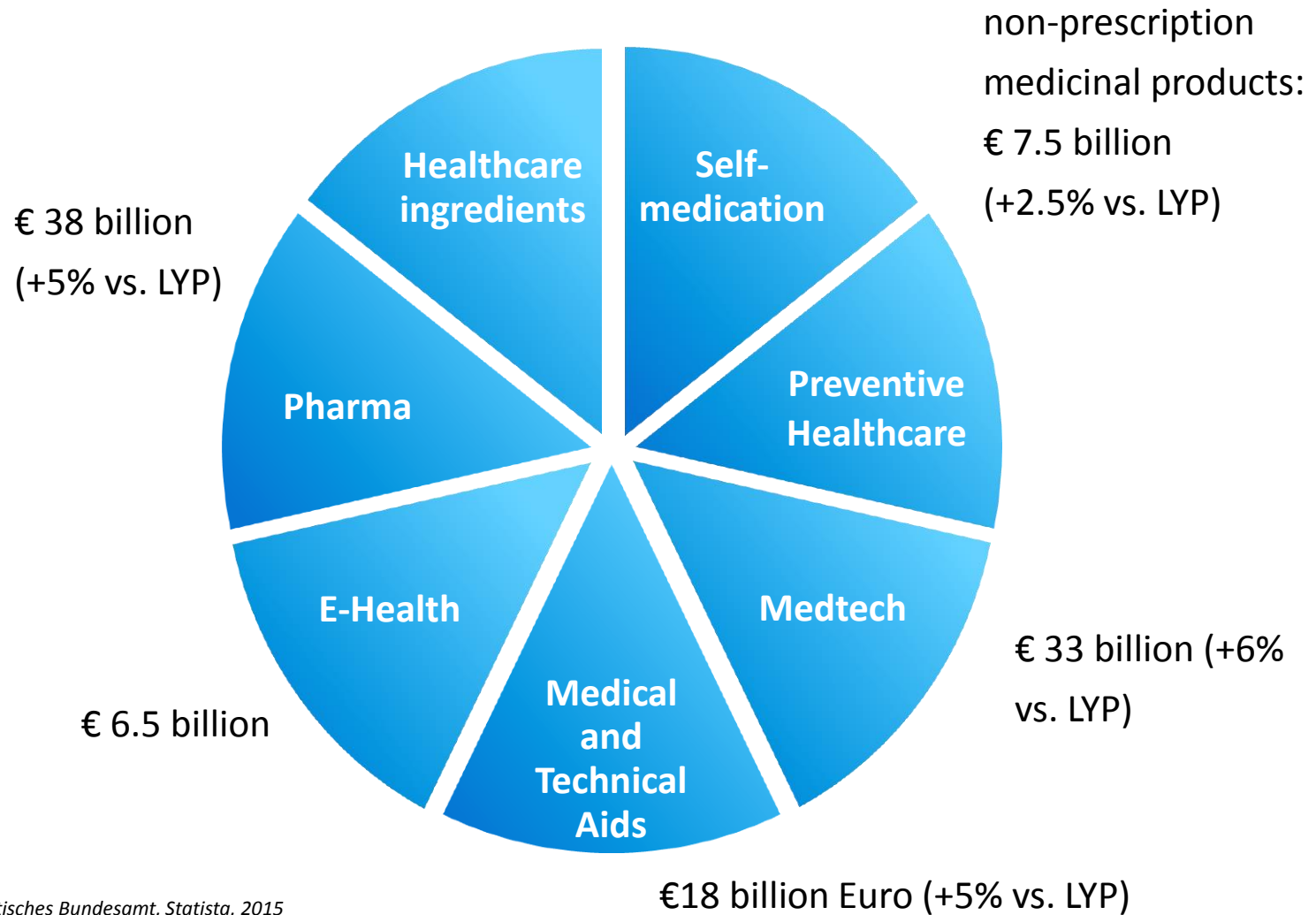
More care patients in an aging society

Number of care recipients in Germany 2003 to 2013 (in 1,000)



Source: Statistisches Bundesamt

Germany's health markets

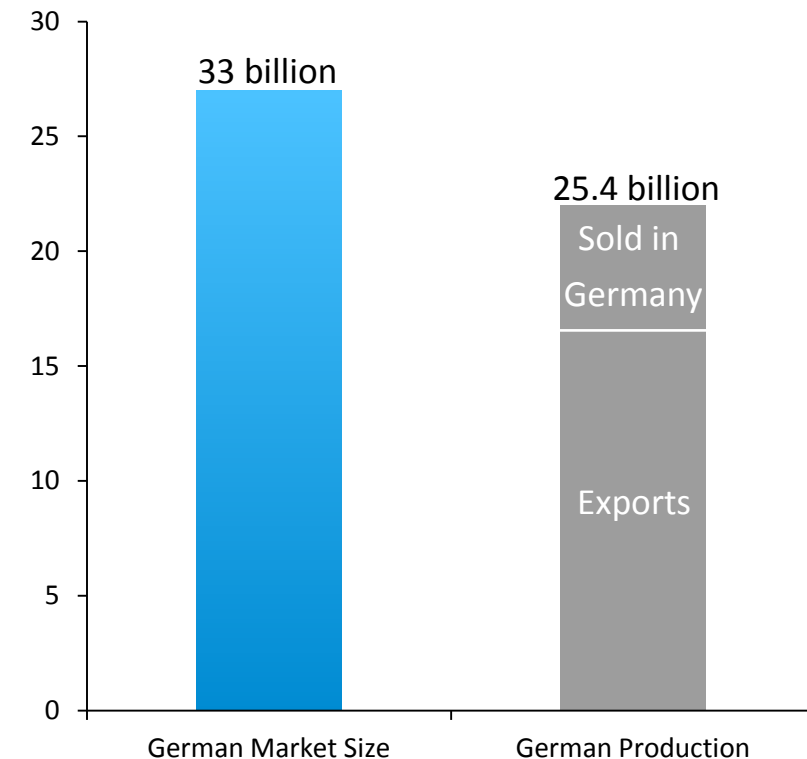


Source: Statistisches Bundesamt, Statista, 2015

Medical Technology Spotlight

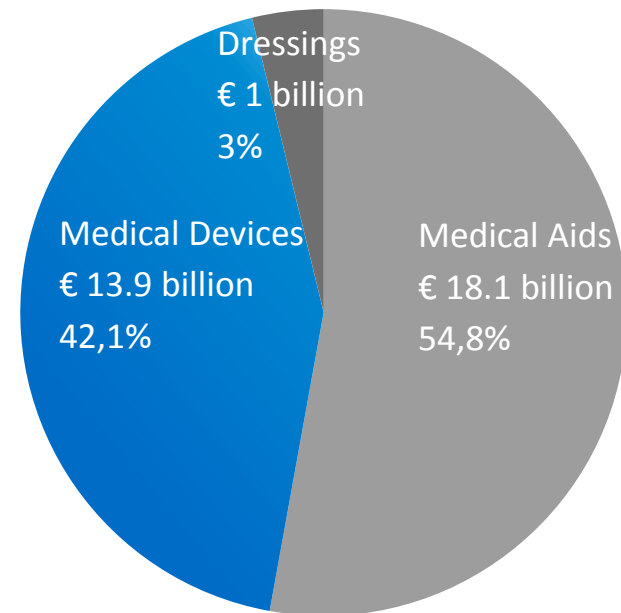
Germany spends € 33 billion on medical technology per annum

Expenses and production



Source: BVMED – Branchenbericht 2016

Market segments in Germany



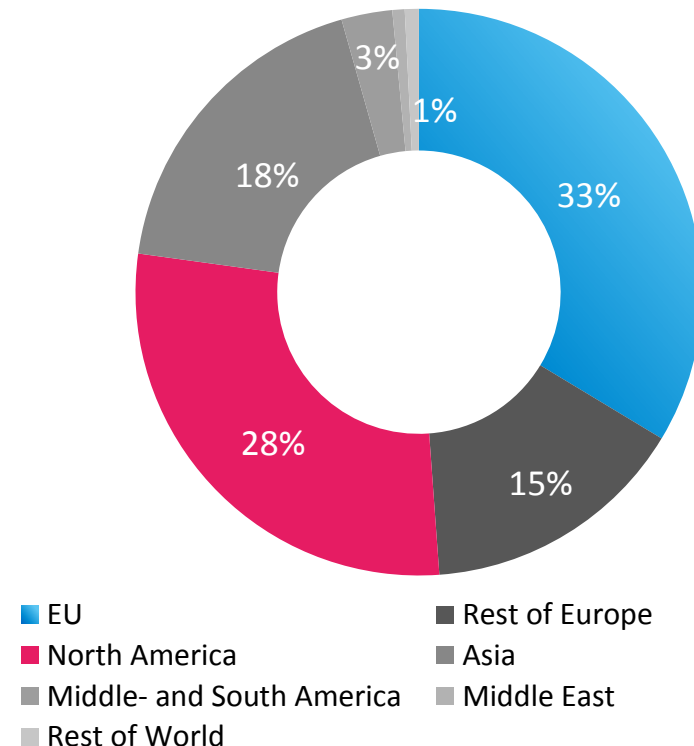
Medical Technology Spotlight

Strong manufacturing – significant imports

Ranking of Products Made in Germany

X-Ray and other radio active apparatus	30%
Devices and Materials for Dental	17%
Prostheses and artificial joint implants	10%
Endoscopes and surgical instruments	8%
Orthopaedic apparatus	6%
EEG and other electrical diagnostic apps	5%
Transfusion and Infusion	5%
Disposables	5%
Medical needs furniture	4%
Artificial kidneys	4%
Apparatus for anaesthetics/breathing	3%
Ophthalmic segment	2%
Wheel chairs	1%

German imports exceed € 10 billion



Source: SPECTARIS Jahrbuch Medizintechnik 2014/2015

Current market trends

Age, Awareness, Technology



Aging Society: Healthful Society

- 2035: 24 million people aged 65 years or older (31 percent of the population)



Innovation: Digitalization

- 2017: German mobile health market worth EUR 3 billion



Care Dependency and Chronic Diseases

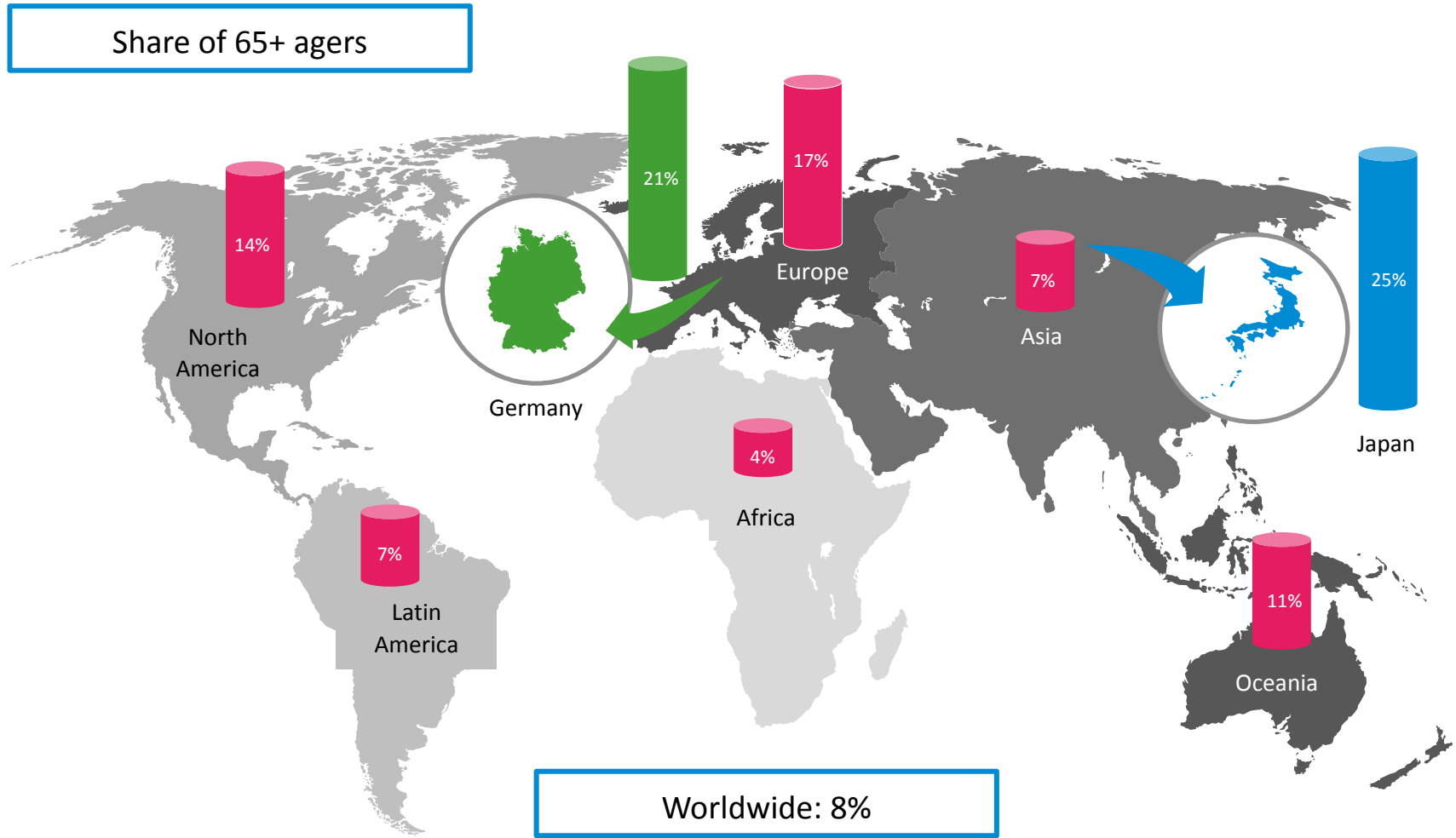
- Chronic and long-term diseases account for about 80 percent of German healthcare spending (EUR 200 billion)
- 2050: 4 million care recipients (+33%)



Source: DB Research 2010, Statista 2014, Statistische Bundesamt 2014

Demographic Change – a Worldwide Trend

Germany has the oldest population within Europe.

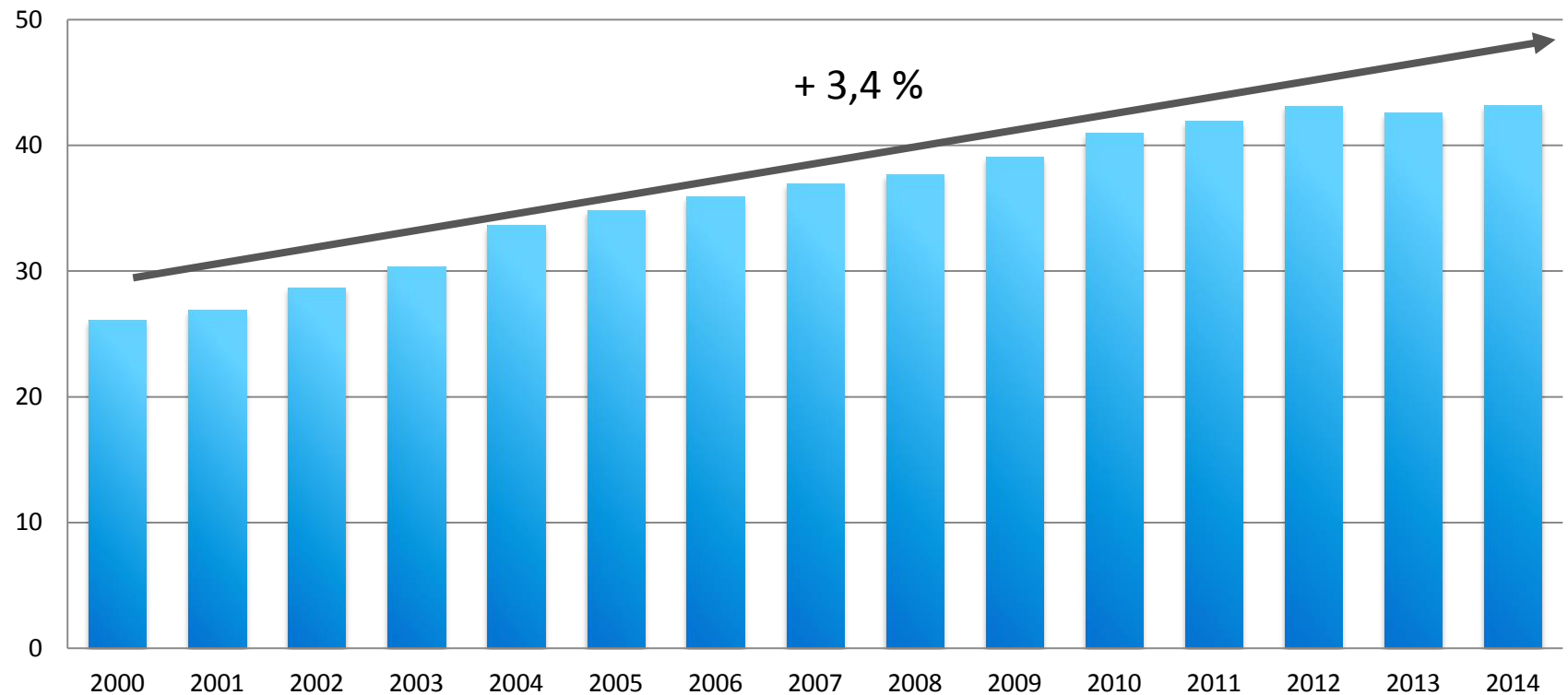


Source: <http://esa.un.org/unpd/popdev/AgingProfiles2013/default.aspx>

Increasing Out-of-Pocket Spending

Golden Agers drive the market

Healthcare expenditures of private households in Billion Euro



Source: Gesundheitsberichterstattung des Bundes 09.05.2015

Progressing Digitalisation

Germany's E-Health Act 2016

2016

The E-Health Act became effective January 1st.

From October on, patients are entitled to receive a medication plan.

2017

A reimbursement scheme will be introduced for tele-consulted X-ray diagnosis (from April on) and video consultation (from July on).

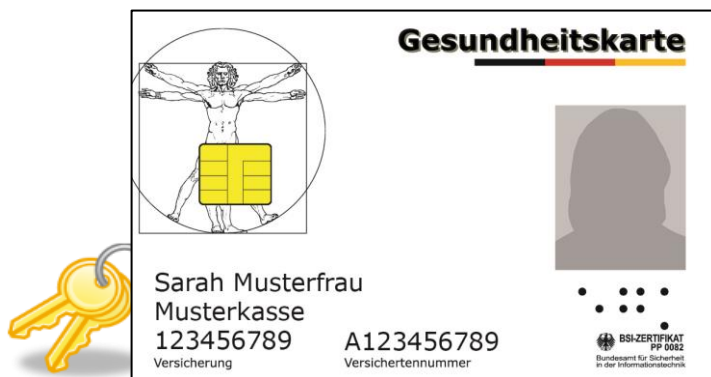
2018

The medication plan will be accessible electronically through the Electronic Health Card.

Emergency data can be stored on Electronic Health Card.

Patients can store their own data (e.g. fitness data) in a patient file.

Gematik has to lay the foundation for the usage of the patient file with the Electronic Health Card to ensure that patient can access their data also outside of the doctor's office.

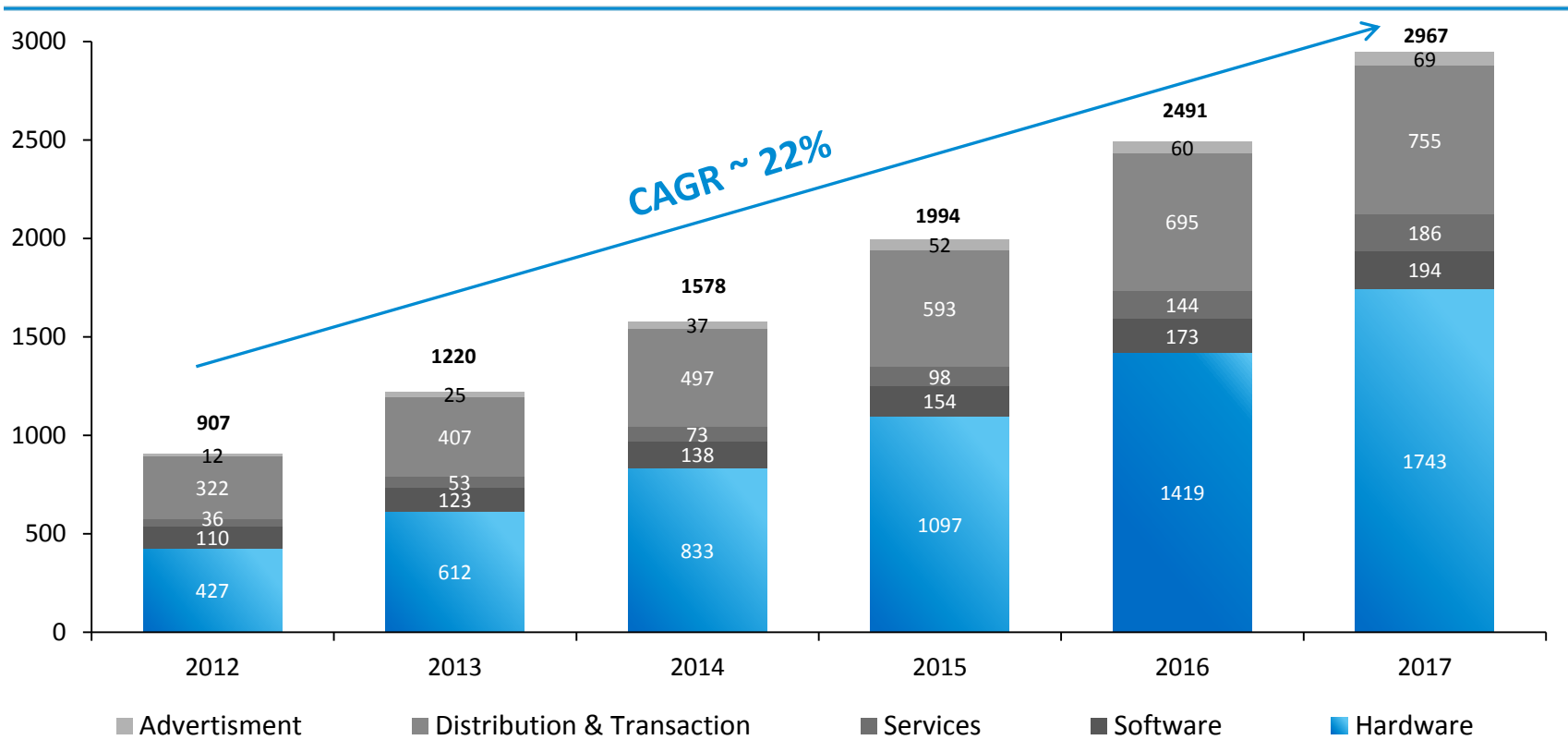


Source: Bundesverband Gesundheits-IT – bvitg e.V. 2016, gematik GmbH 2016

Growth Market M(obile)Health

The German mHealth market will grow to around EUR 3 billion in 2017

Development of the mHealth market in Germany through 2017 (in EUR million)

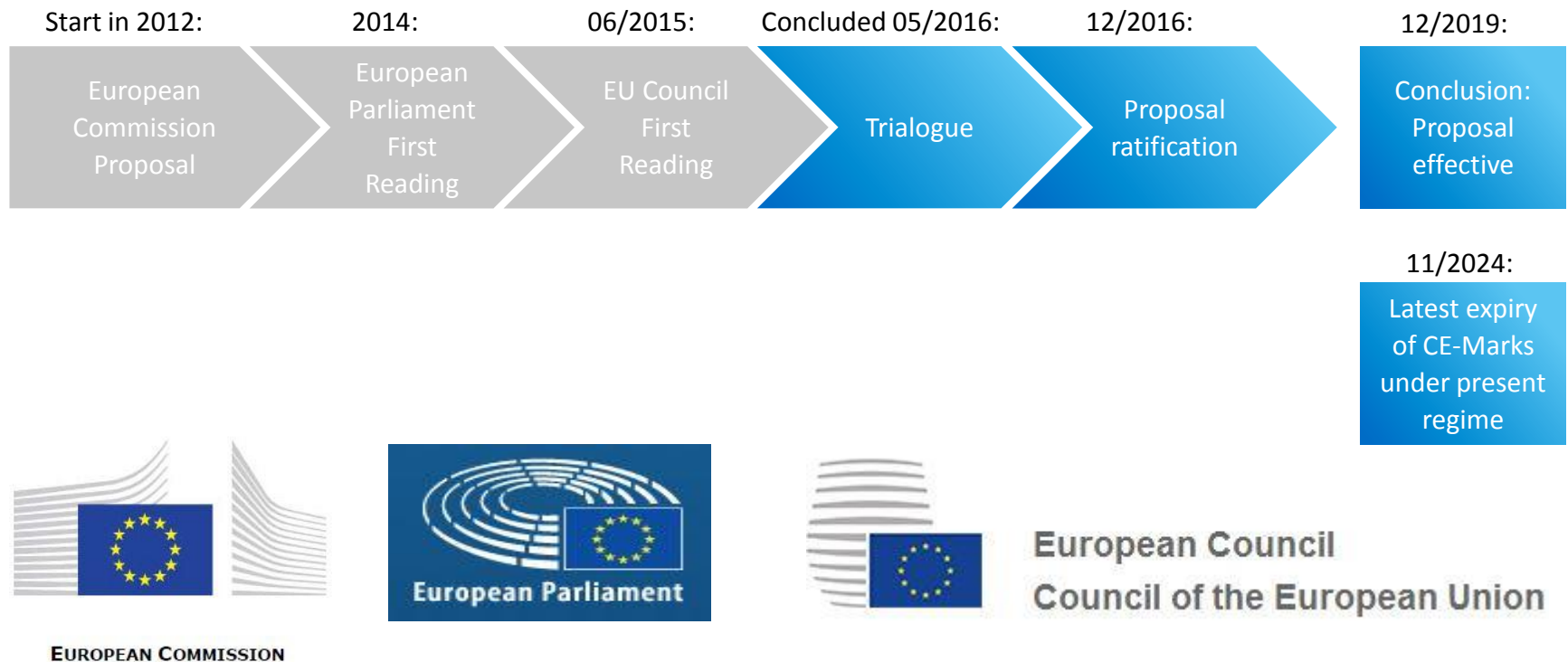


Source: A.T. Kearney 2013

Regulatory and reimbursement opportunities

Revision of the European Medical Device Regulation 2016

Revision Timeline and Involved Bodies



Regulatory and reimbursement opportunities

Revision of the European Medical Device Regulation

CE-Certification: Top Revisions

- Some class I into class II, IIb into class III
- Unannounced (supplier) audits
- UDI database with 21 elements of information per device
- Individual clinical data necessary
- To be published in EUDAMED

New Scrutiny Procedure (III)

Notified Bodies to produce clinical evaluation assessment report **MDCG**



New EU **Expert Committee** may issue **scientific statement** based on **MDCG**



Notified Bodies to incorporate scientific statement, may provide certification with **restrictions**

Regulatory and reimbursement opportunities

Passing Regulatory & Reimbursement in Europe/Germany

European and national Systems

1. Regulatory:

Declaration of EU Conformity (CE)



2. Reimbursement:

Pass National Systems (Germany)

Reimbursement in Germany

In-Patient-Setting:

„Reimbursement unless on negative list“

- Capital Goods(+3 yrs): Direct deal
- Other: DRG-System with lump sums
- Increase via „NUB“ negotiations and „ZE“

Out-Patient-Setting:

- „Reimbursement when on positive list“
- Practice Equipment: Doctor's purchase
- Practice Supplies: Regional clearance (KV)
- Medical Aids: National (GKV)

Regulatory and reimbursement opportunities

The German Medical Technology Clusters play a central role in Germany's medtech innovation landscape.

German Medical Technology Clusters



More than 30 specialized cluster networks focusing on medical technology.

Goal:

- connecting companies, hospitals, universities, and other research institutions
- support continuous innovation in R&D
- help obtain funding for joint R&D projects
- provide shared facilities
- organize educational training programs

Contact Us

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