Medtech market US – opportunities, hurdles, success factors

MEDICA 2019

GTAI GERMANY TRADE & INVEST

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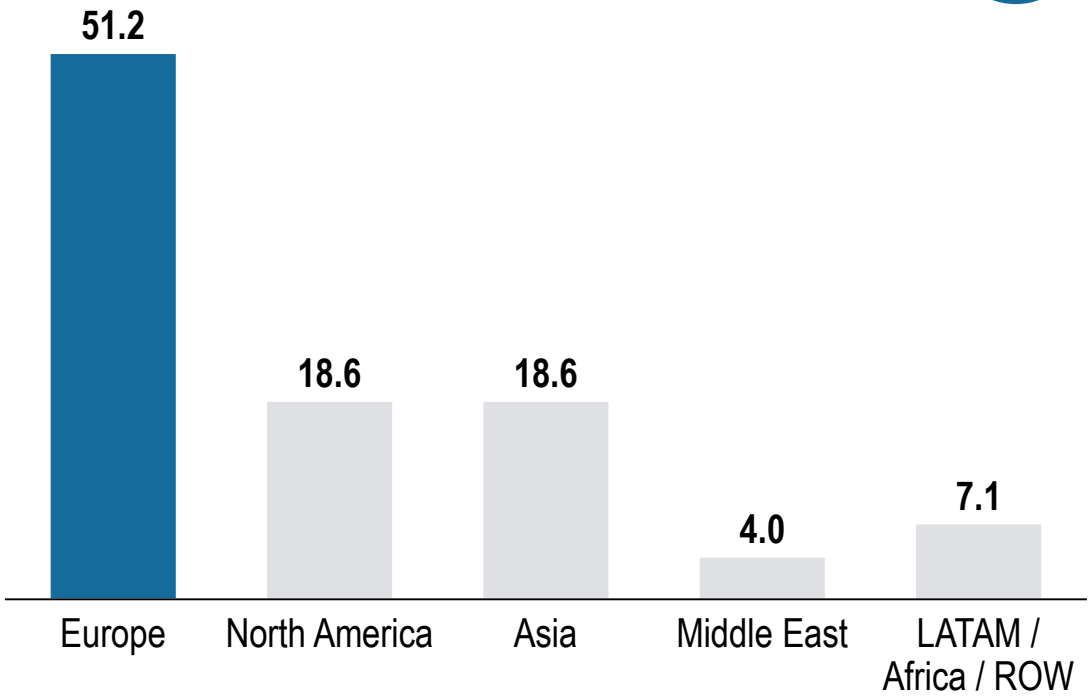
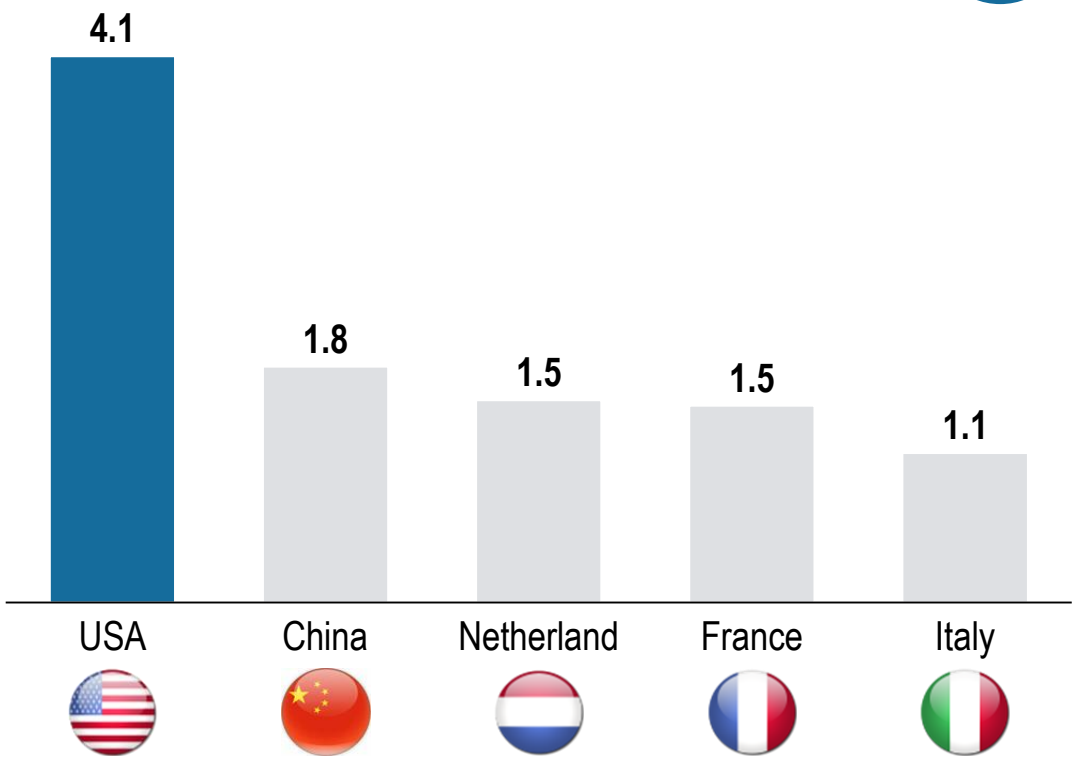
The US is the largest export country for German Medtech companies

Overview of export markets of German MedTech, 2017

Exports by regions [% of total][1)]



Exports by countries [EUR bn]

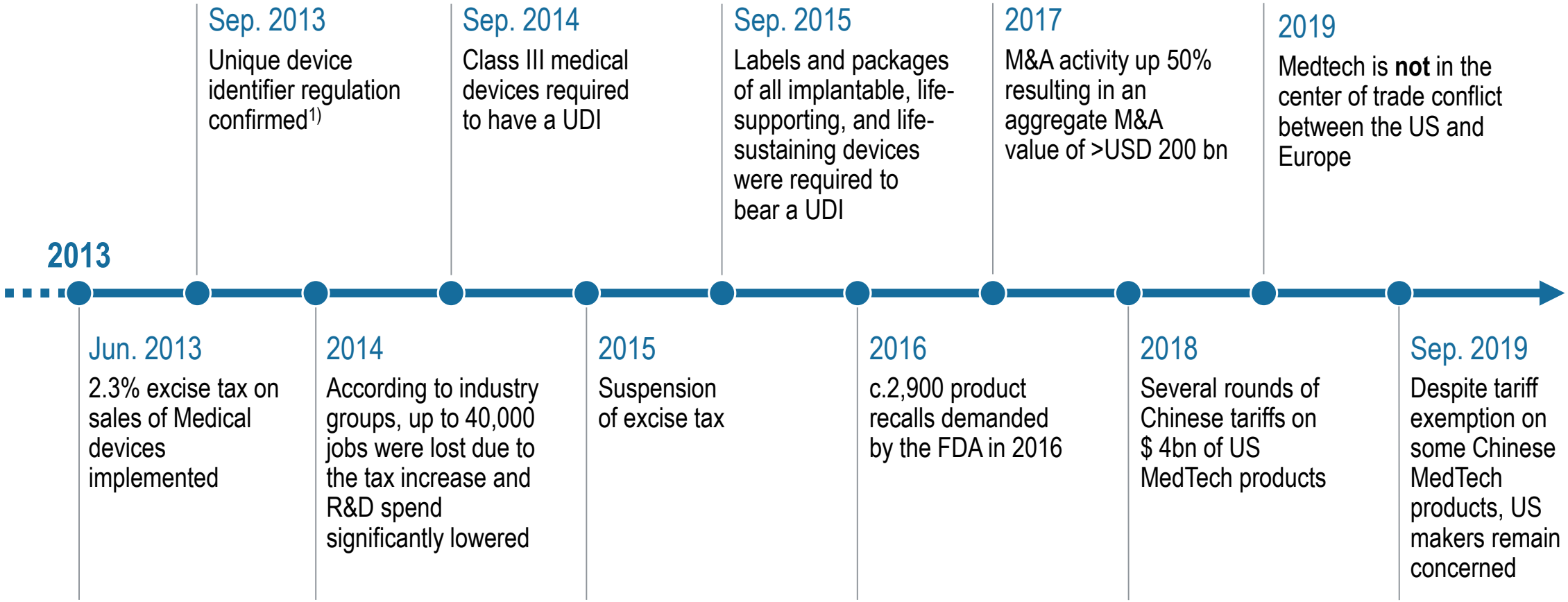


1) Please note: Might not add up to 100% due to rounding

Source: Statista; Roland Berger; German Federal Statistical Office

Main regulatory aspects to be considered in the US are the application of the UDI system, FDA requirements and trade tariffs

Main regulatory developments in the US-MedTech market



1) Adoption occurring gradually

Source: Medpac; FDA; Roland Berger

Future developments stemming from the agreement of Trump and Juncker remain difficult to forecast – Opportunities appear to be larger

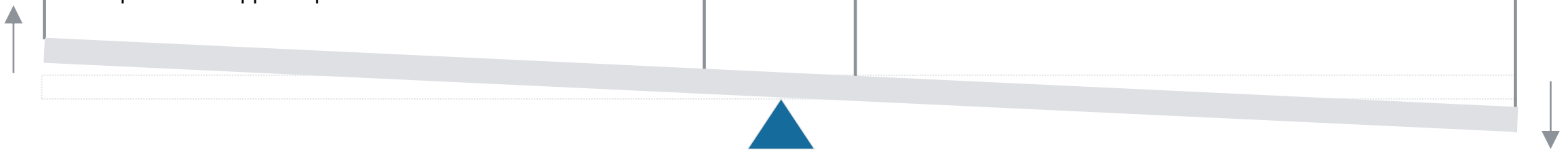
Political discussions

Based on agreement of Trump and Juncker 25 July 2018 and the authorised negotiations stemming from the EU Council Decision of 6 June 2019 could lead to:

- **Registration & admission** processes could become **leaner** and brought **closer together:**
  - > I.e. introduction of a **simultaneous admission** process and/or usage of single audit reports
  - > **UDIs** (Unique device identifiers)[1] systems are planned to be **aligned** based on a bilateral computability test
  - > Yet, EU commission position of 2015 revealed no overall harmonization intended
- **Harmonization** with regards to **safety, QA & QC** processes appears possible

Yet, former discussion from TTIP have already shown that an agreement is depending on multiple factors not only extending to MedTech but also e.g. agriculture

- FDA and EU **overall product registration** process (FDA approval vs. CE mark) are likely to **keep as-is**
- **Liability law (US) vs. regulatory law (EU / Germany)** will continue to remain a key concern for German mid- and smaller sized enterprises



1) UDIs are used to identify and track medical devices placed on the market. A UDI system already exists in the US, and a new system is currently being introduced in the EU

Source: Medizintechnik.de; Roland Berger

The US market offers access to large, innovation friendly customer groups, attractive prices and a growing overall market environment

Overview of key benefits

Market

> The US MedTech market provides a very attractive opportunity with regards to the overall size and its forecasted growth development in the future
> Further, the market is relatively fast in adoption of new technologies providing opportunities for newly developed products

Customer

> Key MedTech customers (hospitals, practices, patients) are in general very keen, savvy and innovation friendly – Digitally enriched business models are further developed than in Europe
> Taking this into account, the US market offers an attractive opportunity to challenge new developments and products

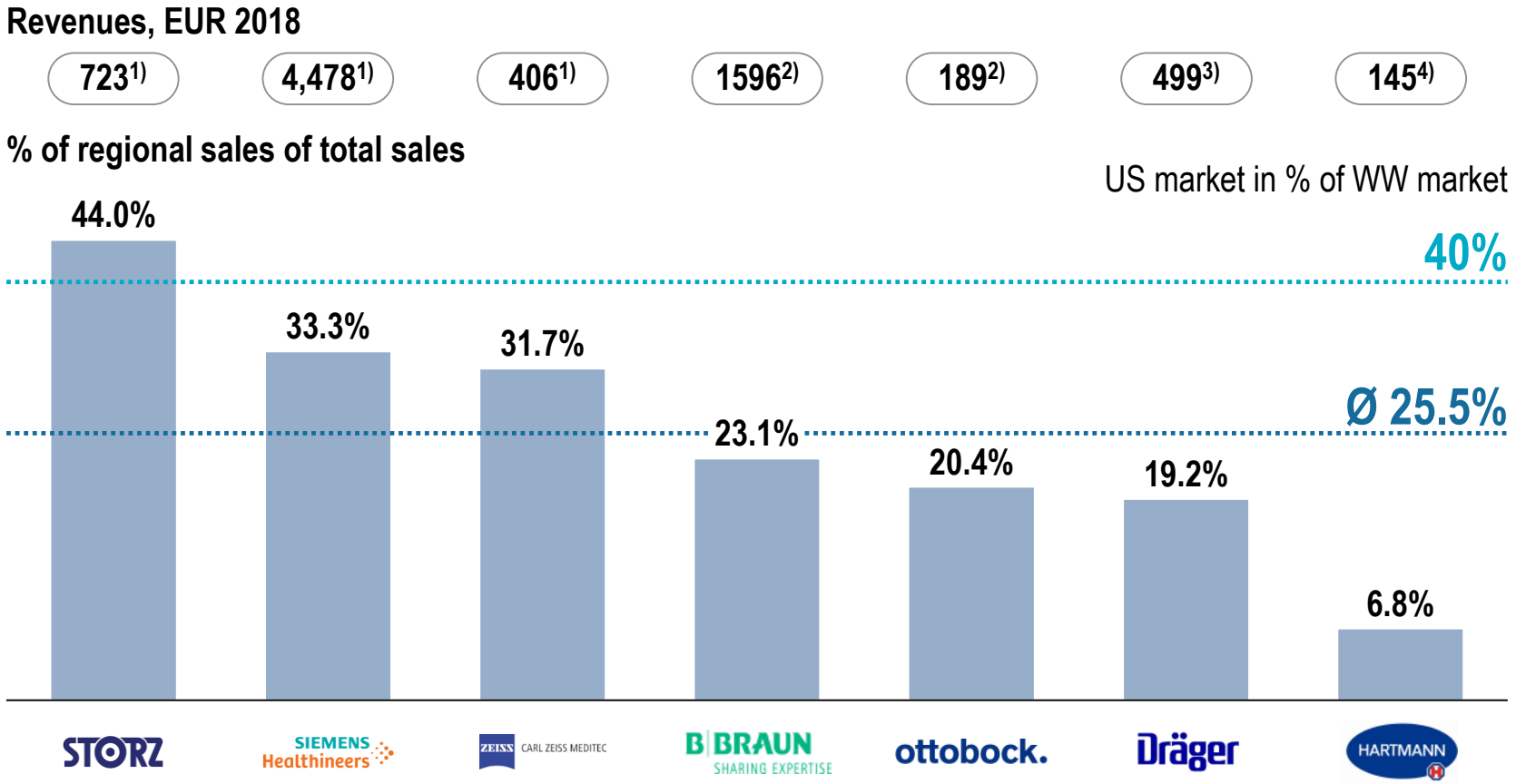
Price

> In general, pricing in the US MedTech market provides upsides compared to difficult European markets if reimbursed by key bodies can be ensures and out-of-pocket payment models are well-developed
> US MedTech per capita spending is still more than twice as high as German per capita spending, driven by attractive pricing

Source: Roland Berger

Performance amongst leading German MedTech in the US varies – Adoption of business model to the US market specifics are key

Performance of leading German MedTech in the US



1) US revenues, Karl Storz with 2017 figures 2) North America revenues, Otto Bock with 2017 figures 3) Americas revenues 4) Northern Europe, America revenues

Learnings

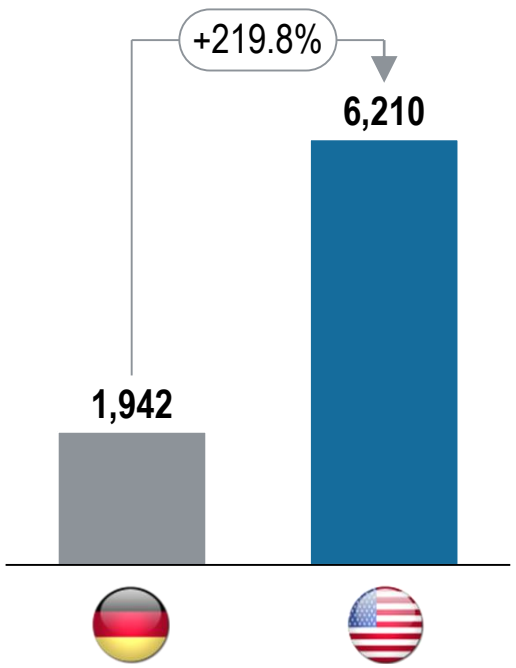
- Strong performance in the US of Storz and Siemens Healthineers is driven by continuous long-term internationalization efforts
- Products & go-to-market approach are often tailor-made or well-tested in the US market
- A strong performance in the US is more difficult if success is based on a regional European business model, e.g. incontinence

Source: CapitalIQ; Frost & Sullivan; Roland Berger; Bundesanzeiger, SelectUSA

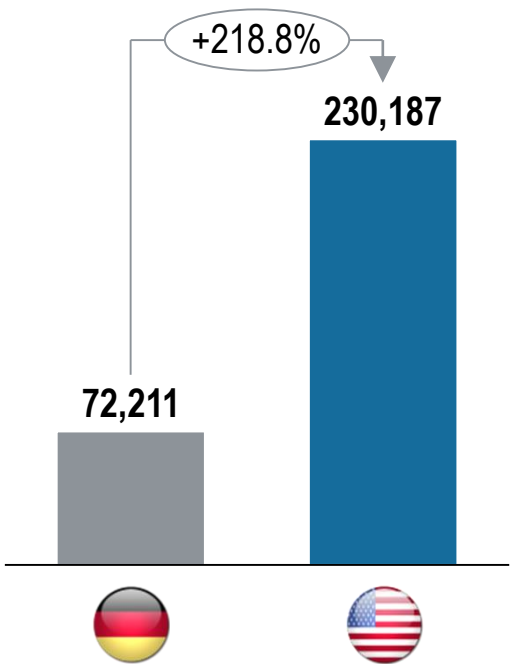
The US represents a sizeable opportunity when compared to the German market with good growth outlook

Significant market opportunity, 2018

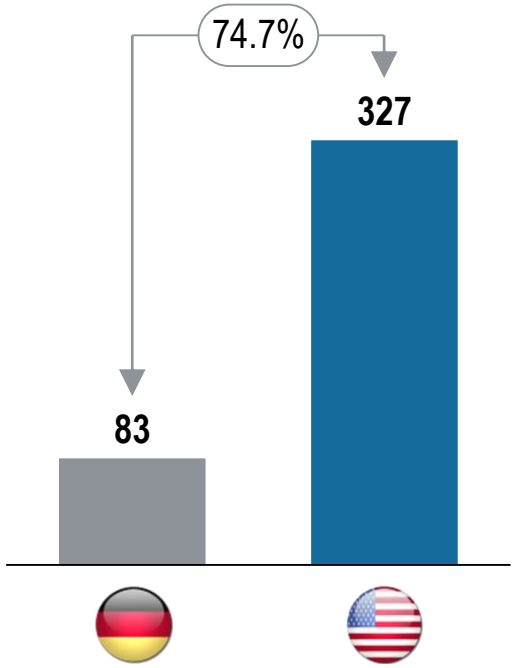
of hospitals, 2017



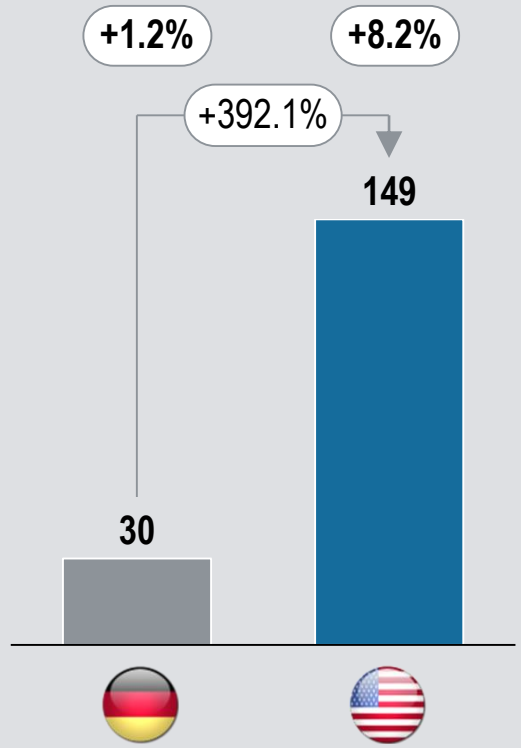
of practices



of people [m]



MedTech market [EUR bn]



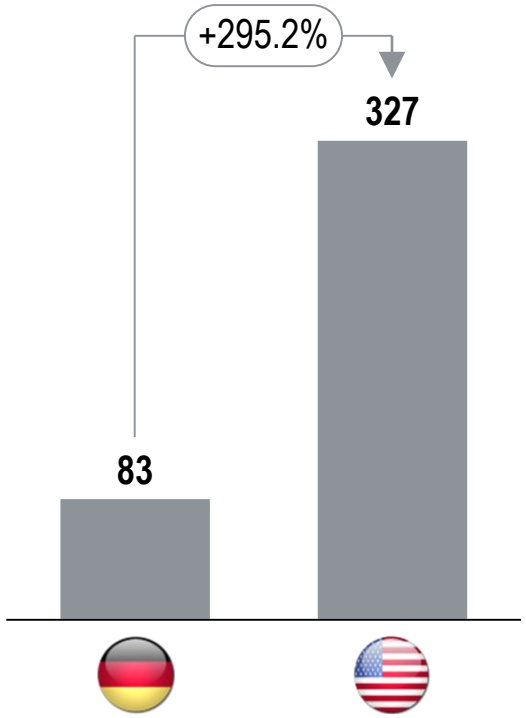
x.x Expected growth rate

Source: Statista; destatis; Worldbank; SK&A; BVMed; Spectaris; Roland Berger

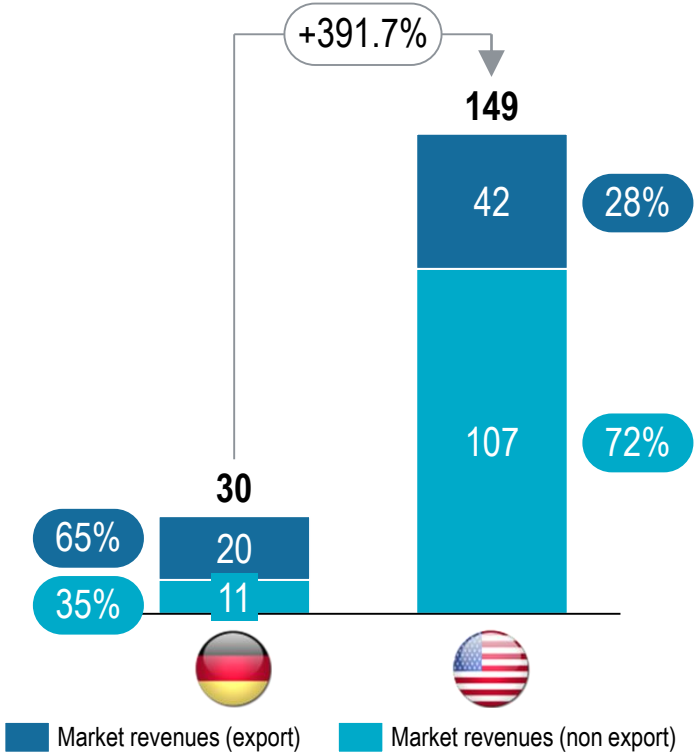
The US MedTech per capita spending is more than twice as high as the German MedTech spending – Attractive pricing as a driver

MedTech spending per capita

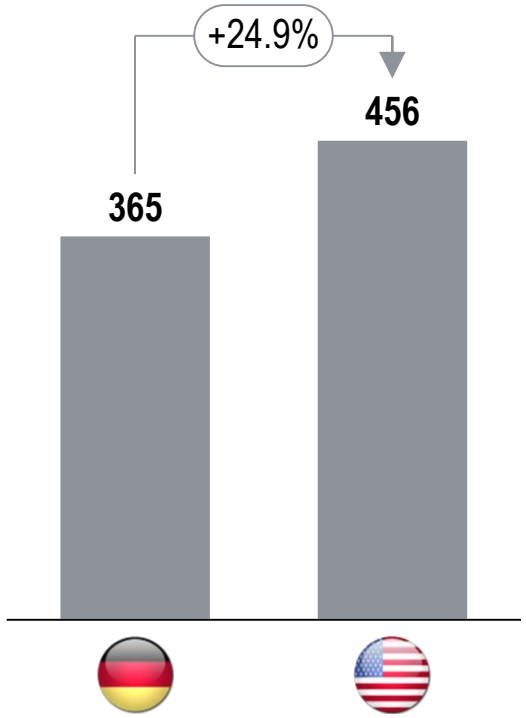
of people [m]



MedTech market [EUR bn][1)]



MedTech p. capita spending [EUR][2)]



1) Please note: Might not add up due to rounding

2) Defined as MedTech market / population

Source: Statista; Nasdaq; Roland Berger

…yet, three key challenges need to be addressed: Fierce competition, regulatory hurdles and setting up a powerful US organization

Overview of key US market challenges

Competition

> Typically, powerful incumbent players with large scale are already active in the US market
> In addition, German MedTech companies operating in the US face competition from new entrants typically with strong IT know-how, such as Google, trying to enter the market

Regulatory / Market Access

> Being regulated by the FDA, the US MedTech market required good quality control & quality assurance schemes to successfully target this market
> Further, key risks with regards to liability law (US) vs. regulatory law (European) need to be mitigated

Organization

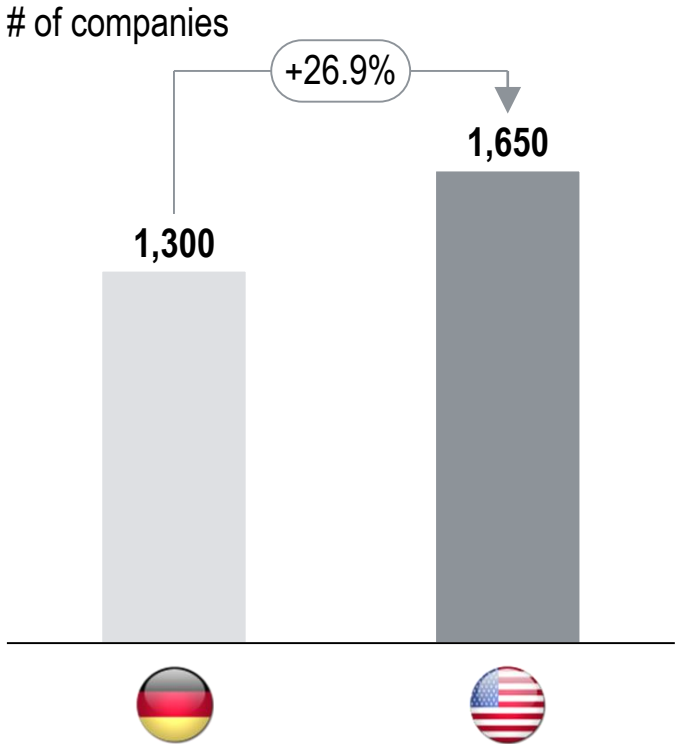
> For German MedTech companies it requires persistent efforts to develop a powerful US organization that is competitive and aligned with HQ
> Best practice case shows how persistence, combined with continuous improvement efforts can lead to strong growth developments of c.10% p.a.

Source: Roland Berger

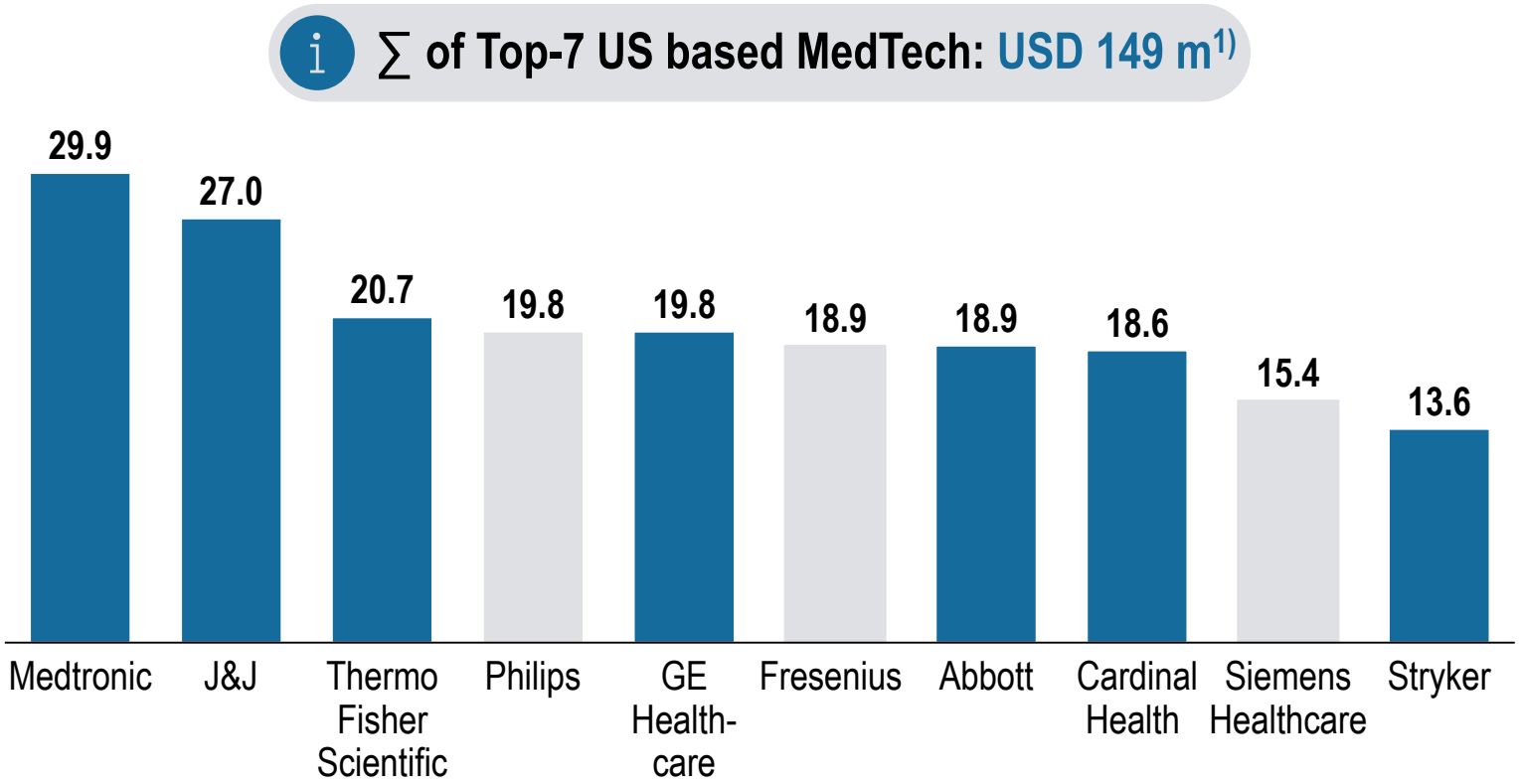
Competition in the US MedTech industry is intense with many strong domestic players

Competition, 2018

German vs. US based MedTechs[2)]



Top-10 MedTech companies



1) Worldwide sales 2) Companies with +20 employees

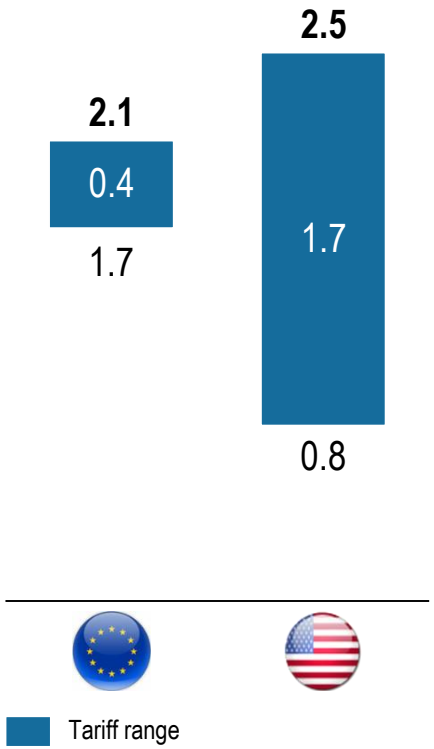
Source: MPO; Roland Berger; Statista

FDA is considered more strict and processes more complex esp. with regard to quality control – Import tariffs with less importance

Regulatory & tax challenges

	US	Europe/Germany
Approval	Centralized	De-centralized
Regulation	State-controlled (FDA – Food & Drug Administration)	Economy controlled – Selected bodies e.g. TÜV / DEKRA
Risk classes	I, II, III	I, IIa, IIb, III
Studies	Clinical studies for class III products (fast track possible)	Clinical studies not required (clinical tests performed)
Criteria	Functionality, safety, efficacy	Functionality, safety
QC / QA & Surveillance	Strict process & quality control requirements	More pragmatic
Law system	Liability law	Regulatory law
Effectiveness	**RB view:** FDA considered more rigorous, yet no clear indication of improved effectiveness	

Import tariffs on medical products [%]



Note:
Some product groups are already tariff exempted for both markets

Magnitude of applicable tariffs still moderate, however toll processes need to accounted for when exporting to the US

Source: Medizintechnologie.de; Roland Berger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