

***Medical devices and in-vitro diagnostics:
A general introduction to Medical Devices in EU***

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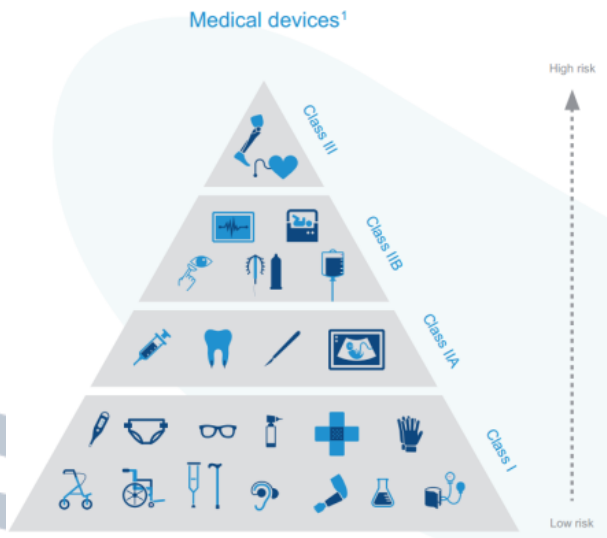
What is a Medical device ?

Medical devices include things like:

- pacemakers
- scanners
- x-ray machines
- dressings or stethoscopes

They're a vital part of modern health systems.

OVER 500,000



Living aids	Instruments for doctors	Delivering drugs	Diagnostic tools	Body replacement parts





MEDICAL TECHNOLOGY IN COMMUNITY CARE

6 BROAD CATEGORIES OF MEDICAL TECHNOLOGY

PREVENTIVE



To prevent disease, injury or other conditions. Used by citizens and healthcare professionals.

DIAGNOSTICS



To diagnose conditions. Used by citizens and healthcare professionals.

INTERVENTIONS



Often used outside of hospital. Used by healthcare professionals.

THERAPEUTIC



To treat patients in the home or after hospital stay. Require support from healthcare professionals. Used by patients and carers.

ASSISTIVE



To manage or restore bodily function. After initial fitting patients and carers take over the care.

MONITORING / E-HEALTH



To treat patients in the home or after hospital stay. Require support from healthcare professionals. Used by patients and carers.

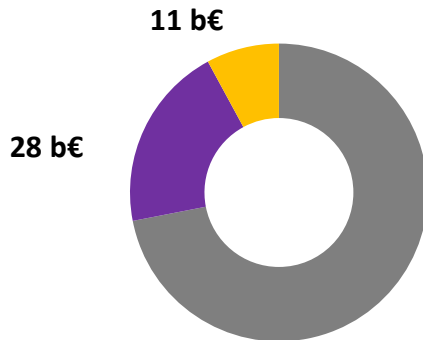
Key figures on Medical devices

Based upon manufacturer prices the European medical technology market is estimated to make up 31% of the world market. It is the second largest medical technology market after the US ($\pm 40\%$)¹³.



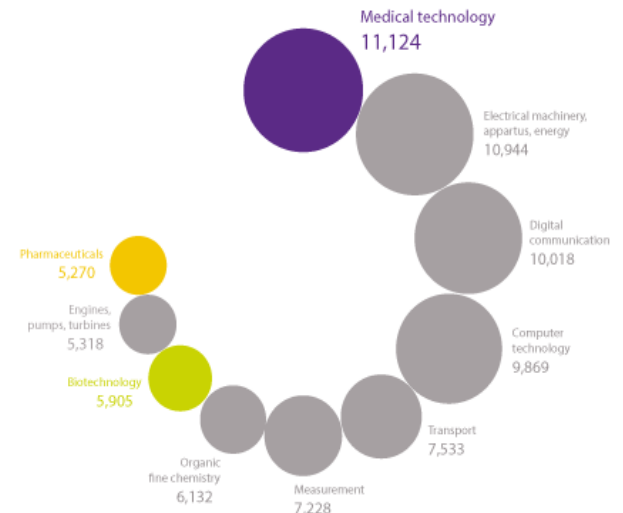
> 575,000 employees

Highly Innovative



- Medical technologies
- ICT & Imaging
- IVDs

Europe has a positive medical technology trade* balance of €14 billion (2014). This is less than in 2013 (€15.2 billion), but still represents a twofold increase since 2006. In comparison, US medical technology trade surplus is at €5 billion. Compared to 2012, the main European medtech trade partners remain the same: the US, China and Japan.¹³



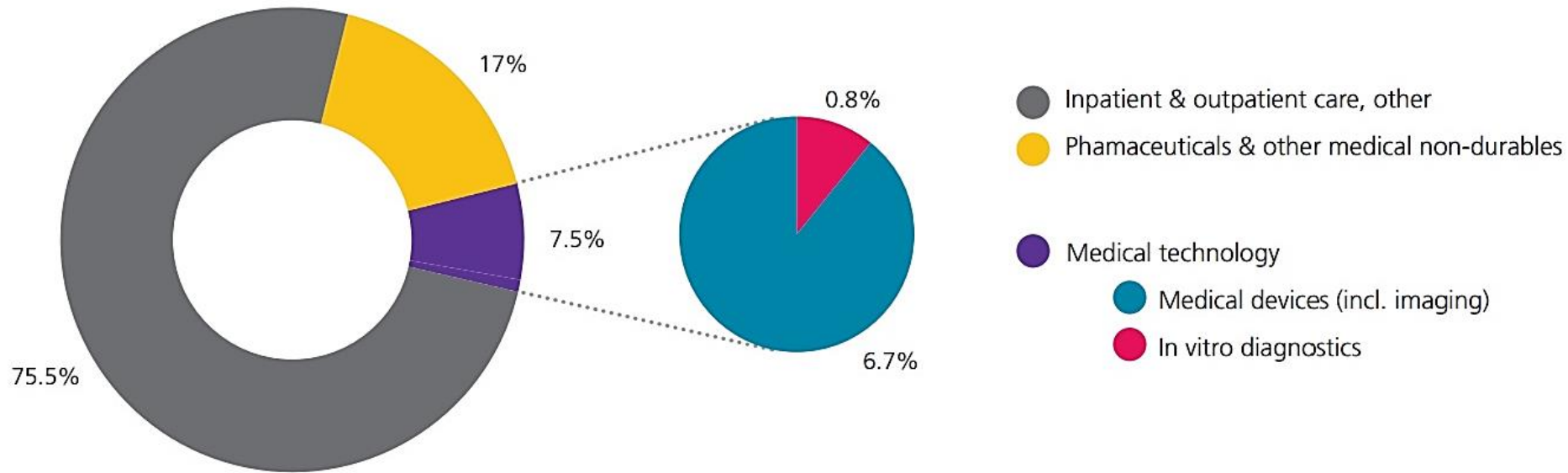
> 80% SMEs

11,000 IN 2014



R&D investments range from 8% to 12% of the revenues

Health expenditures & Medical devices



In Europe, an average of 10.4% of gross domestic product is spent on healthcare. Of this figure, around 7.5% is attributed to medical technologies

Medical Devices : designing a safer system ?

Wider and clearer scope
of EU legislation to
include more products
and clarify what is
covered

Stronger supervision of
Notified bodies

Transparency of data

Clearer rights and
responsibilities
Better coordination
among Member States

Extended database on
medical devices

Improved traceability

Stricter requirements
for clinical evidence

Adaptation of the rules
to technological and
scientific progress

Regulation on re-use of
single use devices

Alignment to
international guidelines



Critical elements of a future proof system

**Keep a Decentralised
system for
authorization**

**Regulation of the
reprocessing of single
use devices**

**Increasing
harmonization and
coordination among
Member States**



**Increasing
transparency**

**Work toward Global
regulatory
convergence**

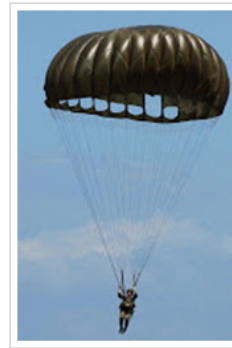


Clinical evidence

Clinical evidence

- Fit for purpose
- Good balance between pre and post-market requirements
- Demonstration of efficacy/Randomized Control Trials ?
- Clinical equivalence restriction for Class III and implants
- Get it right for existing implants and high risk devices

A Call for Randomized Clinical Trials of Parachutes



In the tight-sphinctered world of academic medicine, it's always delightful to find a journal that still has a sense of humor. The following satirical paper from the British Journal of Medicine made me laugh and laugh.



Smith GCS, Pell JP. (2003). Parachute use to prevent death and major trauma related to gravitational

challenge: systematic review of randomised controlled trials. *BMJ*, 327 (7429), 1459-1461. DOI: [10.1136/bmj.327.7429.1459](https://doi.org/10.1136/bmj.327.7429.1459)

In a nutshell, this paper rightfully points out that no one has ever done a randomized, controlled trial (RCT) on the efficacy of parachutes. Furthermore,

Advocates of evidence-based medicine have criticised the adoption of interventions evaluated by using only observational data.



Case by Case approach
Common Specifications
Well-established technologies