

medídee®

Regulatory & Clinical Affairs
Quality Management

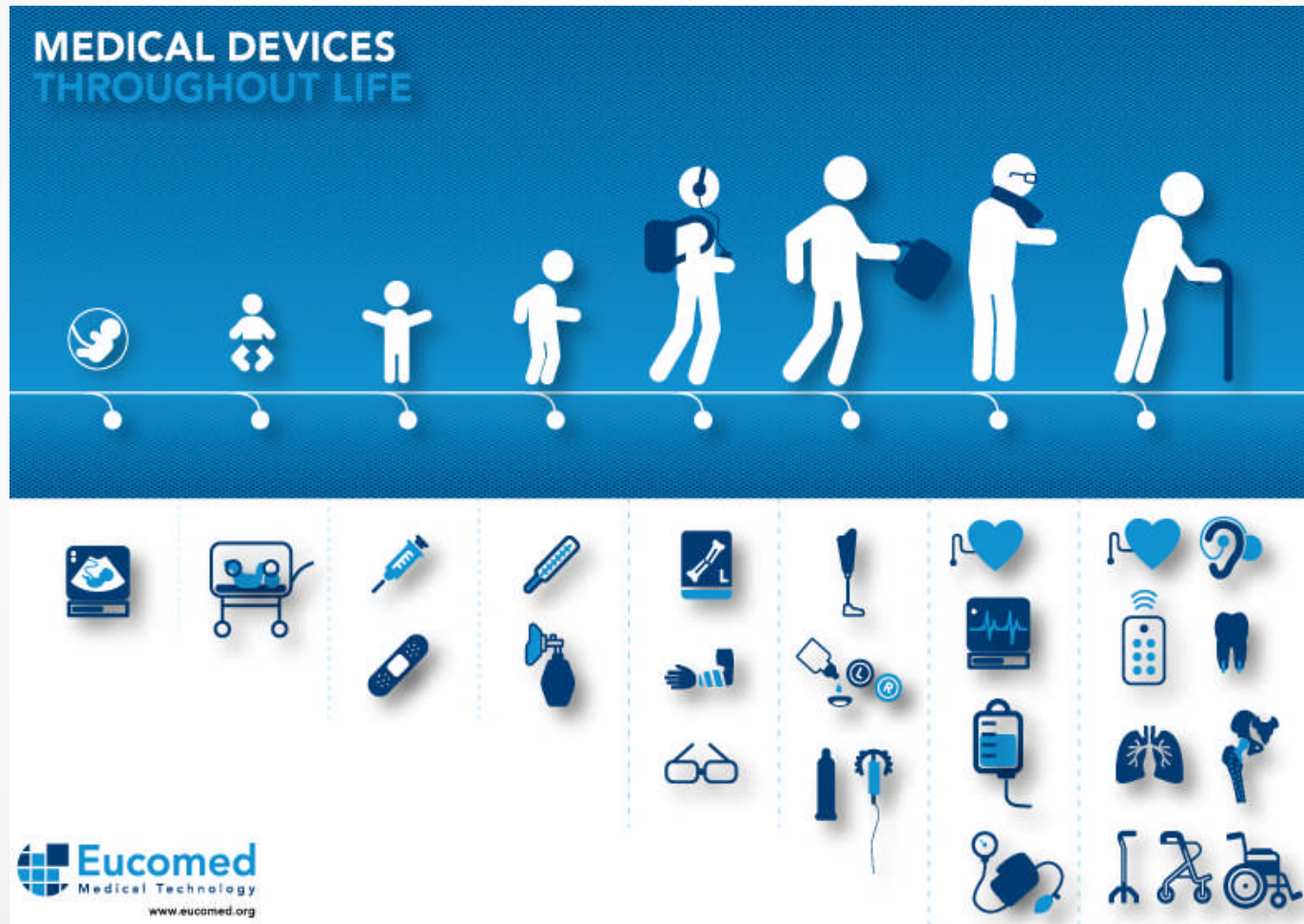
Nano-Tera.ch

05 February 2015 – part 1

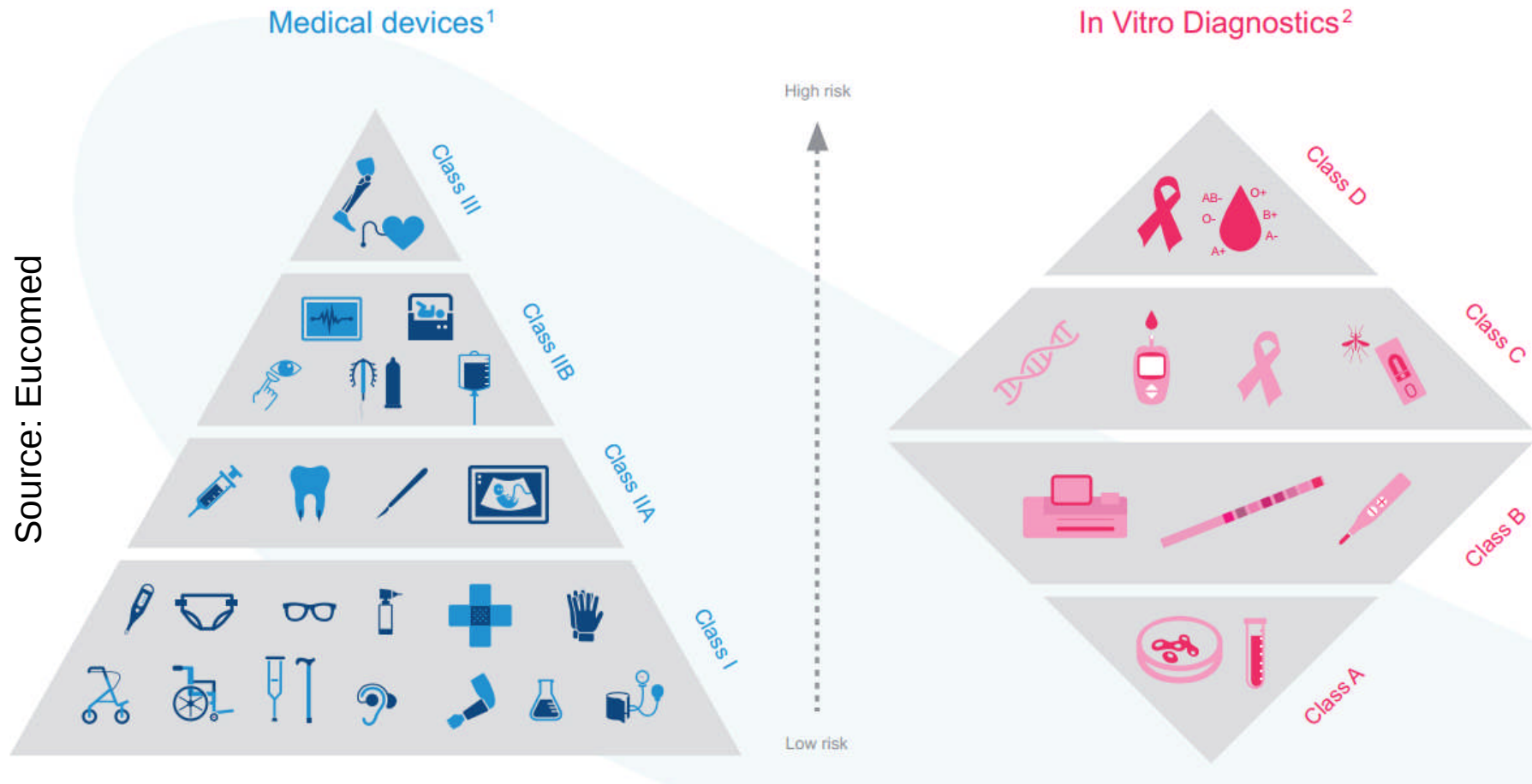
Introduction Medtech

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Medical devices throughout our lives



Diversity and classification of medical technology

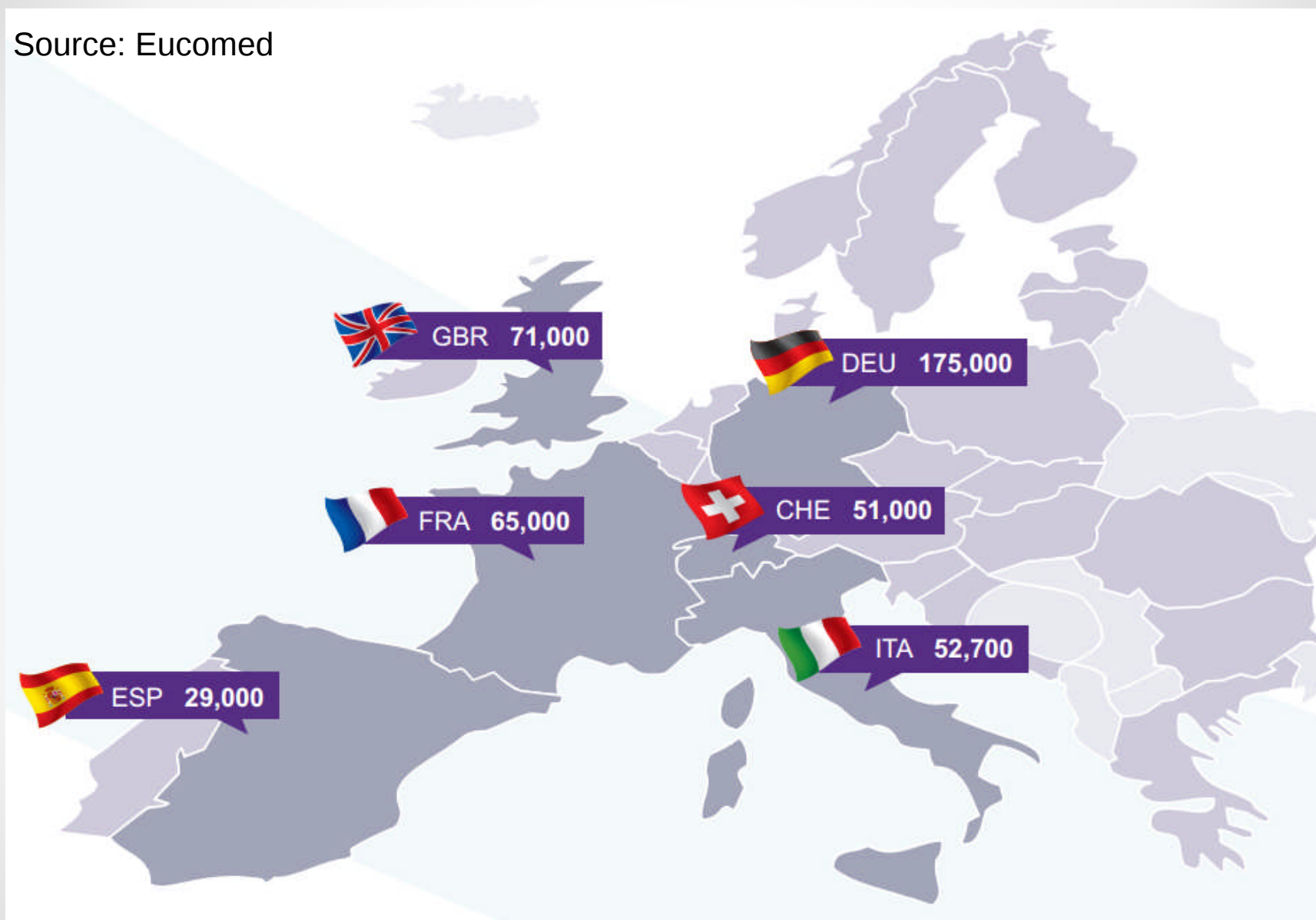


Source: Eucomed

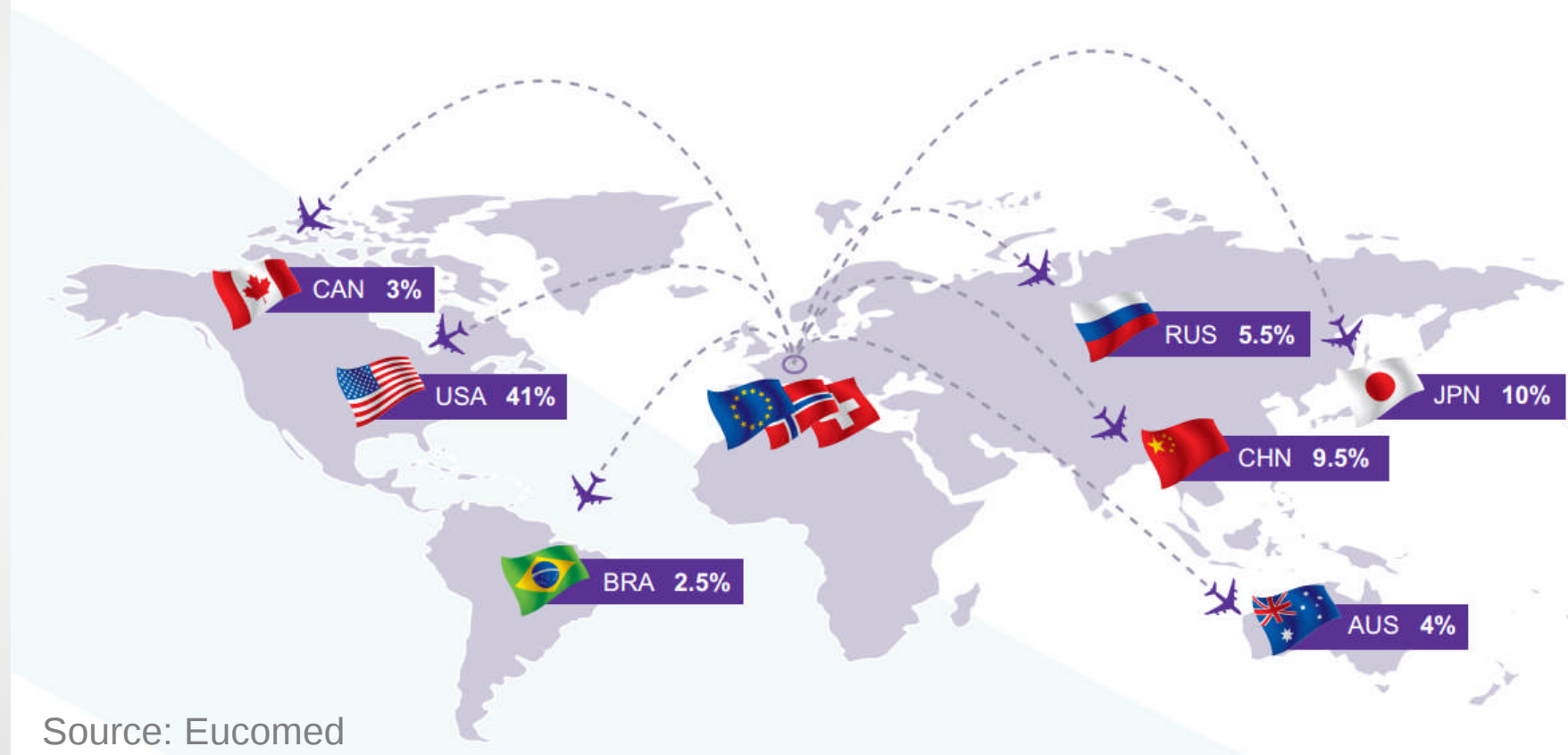
Top 10 technical fields in patent applications. Number of patent applications filed with EPO, 2013 ⁵



Source: Eucomed



Top European medical technology export destinations, 2012 ¹¹



EU Medtech facts

- > 25'000 Medtech companies
- > 575'000 Employees
- 90% SMEs
- 0.8% of GDP spent on Medical technology
- Average €195 per capita (US: €380)
- Medtech Market EU 100 billion
- 28% of world market (US: 40%)

Source: Eucomed

Swiss Medtech facts

- > 1'400 Medtech companies
- > 52'000 Employees
- 90% SMEs
- Ca. 14 billion CHF sales
- Medtech sector per capita : 3x times bigger than Germany
- ISO 13485 certifications 8 times more than average EU per capita

Source: Eucomed, Swiss Medtech Report, Medical Cluster SMTI

20- Finalize Reimbursement

19- Market Clearance, PMA,
510(k), CE...

18- Finalize tech doc, STED, DHF,
DMR, Design Dossier

17- Design Validation: perfor-
mance, clinical evidence, prepare
PMS plan

Scale up manufacturing

16- Reimbursement Strategy

15- Freeze DMR 1

14- Update Regulatory Path /
Strategy - Contact reg. Body

13- Design Verification features
/components, finalize pre-clinical
testing, safety evidence

11b- Design activities features &
components

1- Product Idea

2- Is there a market ?

3- Proof of Concept

4- Concept Risk Analysis

5- Set up QMS for activity

6- Start Risk Mgmt activity

7- Set up Design Inputs: URS

8-How big is market really when
having exact URS ?

9-Define Regulatory Pathway –
contact “regulatory Body”

10- Set up Design Inputs: FRS
(+URS) under Design Control

11a- Start design activities
Features / Components

12- Still a market
with what is
achievable ?

End of part 1. Introduction Medtech

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Followed by part 2 Terminology – Glossary – Definitions (PSO)