

# MDR-UPDATE

**MEDICA 2024 GTAI PAVILION, TUESDAY, NOV. 12TH**

**14:00**

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# Medtech is in high demand

€42 bn

Market volume 2023

1480

Manufacturers (20+ empl.)

2/3

Exports: „Made in Germany“ sells

1374

Leading patent applications at EPO

€23 bn

Imports: high demand (2022)

CE

Medical Device Regulation (MDR)



# CE certification

## MDR is in effect but under construction

- Certification of Notified Bodies, legacy and new products
- White-Paper by associations BVMed and VDGH (June 2023)
- EU representatives visit cluster Medical Mountains (June 2024)
- European Parliament resolution „Urgent need to revise the medical devices regulation” (October 2024)



# EU and national regulation

## EUDAMED and DMIDS

- German implementation “MPDG”
  - medical devices operators ordinance (*MPBetreibVg*)
  - medical product advisor (*Medizinproduktberater §83*)
- European EUDAMED becoming mandatory in 2026
- German DMIDS already mandatory (MPDG §86)

# Market Access for Innovative Devices

## Clinical trials for CE (MDR) validation: Cash grants available

- For innovative class II/III
- Grant for training phase
- Grant for innovation phase
- Max. 70% of costs applicable

VDI Technologiezentrum

BEAUFTRAGT VOM  
Bundesministerium  
für Bildung  
und Forschung

### Call for applications: Clinical evidence for medical devices

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graph TD; SME((SME)) --- clinic((clinic / study site)); SME --- IIP((IIP)); SME --- BfArM((BfArM Ethics C.)); SME --- CRO((CRO)); SME --- others((others));
```

Funding rate	Financing volume/(period)
<ul style="list-style-type: none"><li>• Training aid: 50 % + boni</li><li>• Innovation aid: 50 %</li></ul>	<ul style="list-style-type: none"><li>• demand-oriented</li></ul>

Endpoints
<ul style="list-style-type: none"><li>• Modul 1: Application for clinical trial BfArM</li><li>• Modul 2: End of clinical trial</li></ul>

IIP: Industry in Clinic Plattform

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# Germany's medtech clusters

## Innovation Cluster Survey

### Key networks facts & figures:

- 17 networks in survey
- 3000+ member companies
- 35 member university hospitals
- Key networks topics:

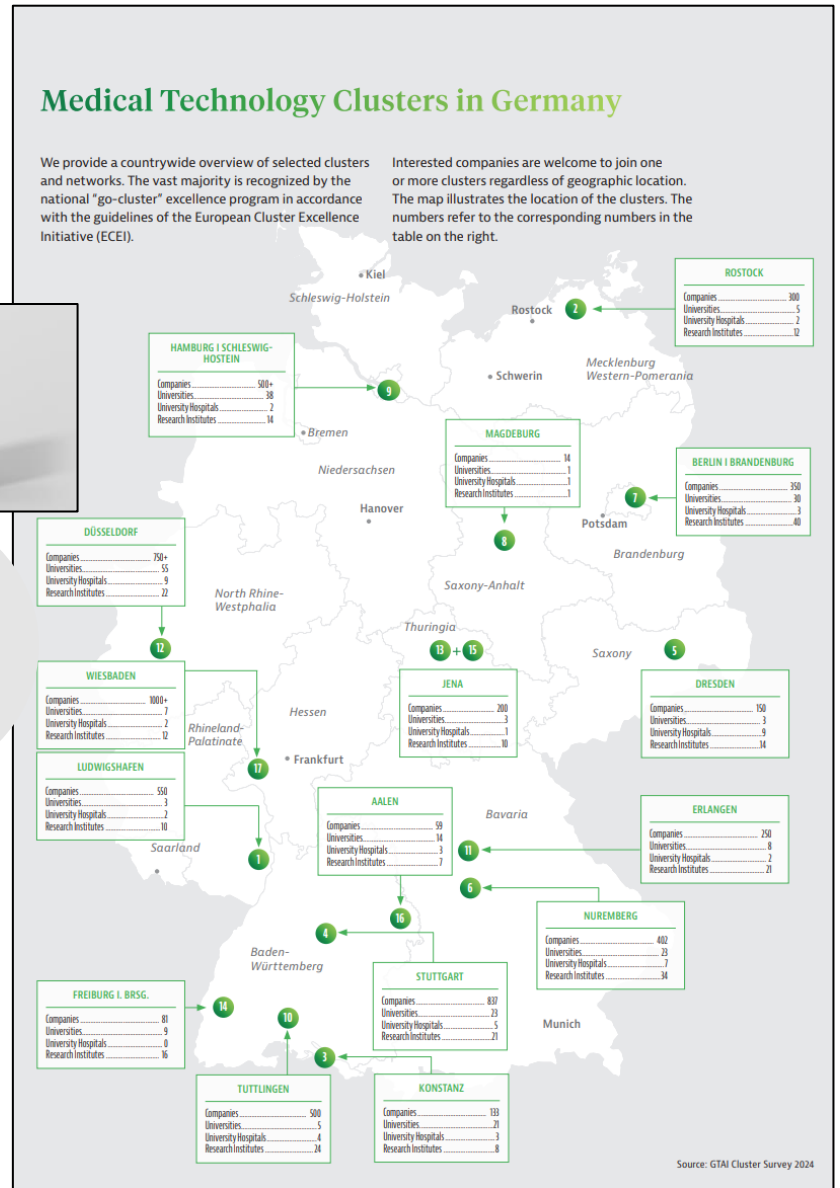
#1: Digital Health, Diagnostics

#2: Medical Imaging

#3: Implants



Available at  
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Supported by the Federal Ministry for Economic Affairs and Energy  
on the basis of a decision by the German Bundestag.

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