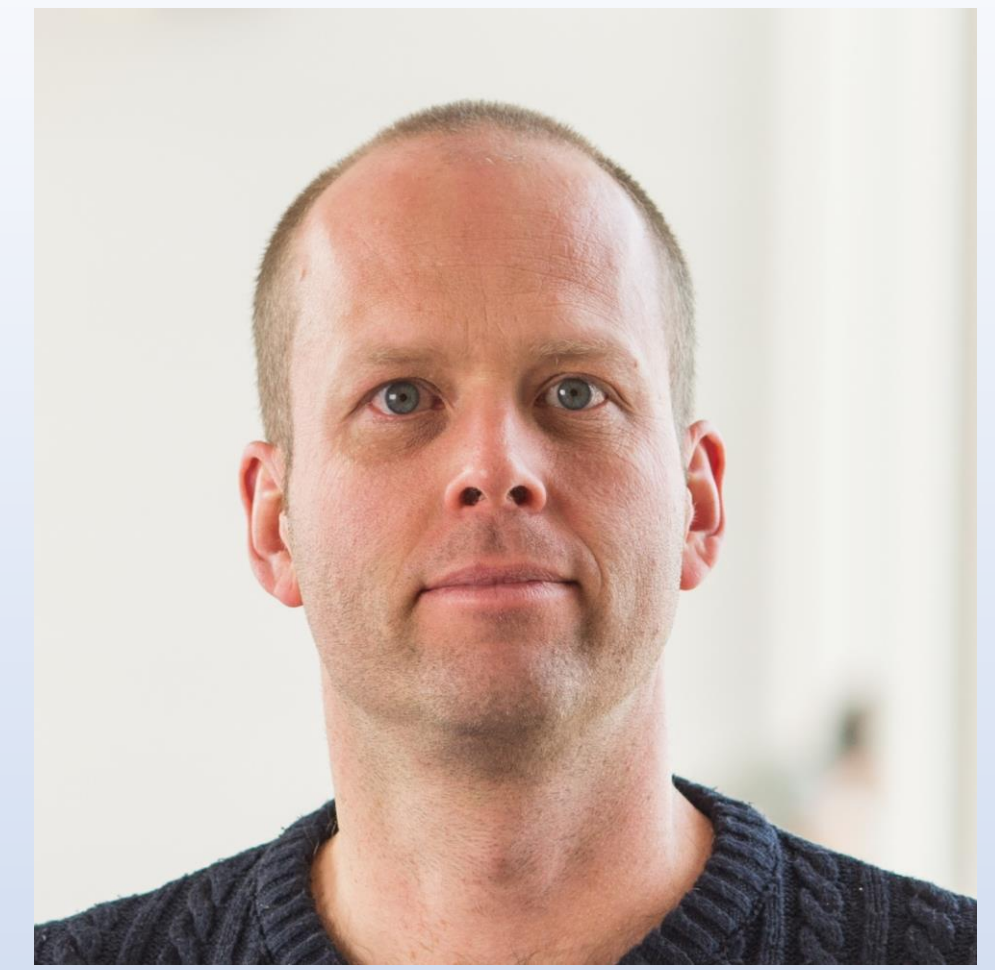


# HCM Regulate

[info@HCM-regulate.com](mailto:info@HCM-regulate.com)



Frank Walboomers, PhD

# New MDD / MDR will have drastic impact on medical device translation from R&D to market

- May 2020 → new MDD (93/42/EEC) & Directive on Active Implantable Medical Devices (90/385/EEC)
- Implementation new MDR, stepwise, ... ?
- **Unclear** to most MD manufacturers
- Expectation that the **number** of lab test in MD will drastically increase, or even quest for development of **new test methods**



The screenshot shows a page from the Dutch government website (Rijksoverheid). The page title is "Nieuwe wetgeving medische hulpmiddelen". The main text discusses the implementation of new European regulations for medical devices (MDR) and in-vitro diagnostic devices (IVDR). It mentions that these regulations will affect manufacturers, importers, and distributors, and that products may be reclassified into different risk classes, requiring them to meet stricter safety and quality requirements. The page also includes links for "Gevolgen voor fabrikanten", "Gevolgen voor gemachtigden, importeurs en distributeurs", "Meer informatie", and "Planning nieuwe wetgeving medische hulpmiddelen".

Rijksoverheid

erpen > Medische hulpmiddelen en technologie >

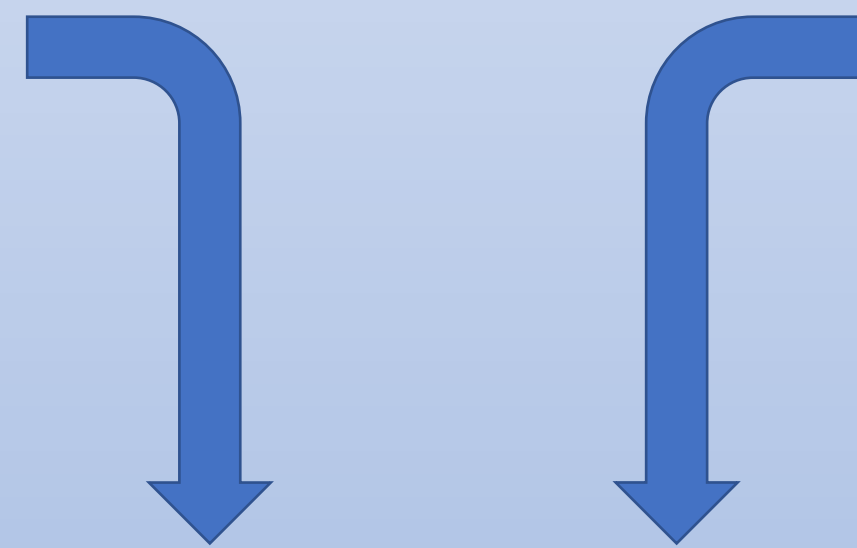
## Nieuwe wetgeving medische hulpmiddelen

Er zijn nieuwe Europese regels voor medische hulpmiddelen (MDR). En voor medische hulpmiddelen voor in-vitro diagnostiek (IVDR). De nieuwe regels hebben gevolgen voor fabrikanten, importeurs en distributeurs van medische hulpmiddelen. Zo kan een product in een andere risicoklasse vallen en moet het voldoen aan strengere veiligheids- en kwaliteitseisen. De nieuwe regels hebben ook gevolgen voor zorginstellingen, zorgverleners en (indirect) voor patiënten.

- > Gevolgen voor fabrikanten
- > Gevolgen voor gemachtigden, importeurs en distributeurs
- > Meer informatie
- > Planning nieuwe wetgeving medische hulpmiddelen

# HCM-Regulate B.V.

- Founded 21/09/22
- Operational per 2023



**Radboudumc**





# HCM Medical B.V.

- Hightech Contract Manufacturing Medical
- Contract Manufacturing Organization (CMO) specialized in the development and manufacturing of biological and biomaterial products.
- Licences: ISO 13485 (Medical Device), Tissue Establishment (allografts), GMP for Investigational Medicinal Products (IMP).
- Facilities: GMP class A/B/C cleanrooms
- Core technologies: supercritical CO<sub>2</sub> technology, aseptic processing, Freeze drying, filling and packaging

# Current capacity

- 650m<sup>2</sup> state-of-the-art biomedical device materials research lab
- Fully compliant to national and international standards of (bio)safety etc.
- High degree of work organization (Digital labjournals, SOP's, ISO/GLP)
- 7 trained and skilled research technicians

# Technical capacity (& this is even partial ....!)

- **Materials synthesis and processing:** Organic/ inorganic scaffolds, gels, cements, dental materials, fibers, coatings, membranes, suspensions, nanoparticles, composites, etc. Thin film deposition (Magnetron Sputtering, Electrodeposition, electrospinning, emulsification, ultrasonication, sintering, plasma treatment, ...)
- **Physico-chemical characterization:** HLPC, electron microscopy (scanning and transmission), DLS, elemental analysis EDS, molecular analysis FTIR, XRD
- **Mechanical characterization:** Tensile benches static/dynamic from 10 to 20.000 N, rheology, profilometry, surface properties (roughness, scratch tests, etc), erosion/ageing/wear simulation, ...
- **Cell & Molecular Biology:** GMO-certified cell culture lab, live imaging, mechanical loading, molecular biology including (q-PCR , ELISA, blotting, etc.)
- **Preclinical studies & Histology:** (small & large in vivo models), paraffin embedding + immune stainings, PMMA embedding and diamond blade sawing microtomes to section hard matter, automated microscopy & DIA
- (clinical studies)



over 100 machines / techniques operational; many unique to medical device research

What can **HCM**  do for you  
Regulate

