

# • Mecuris Manuel Opitz

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force in May 2017, provides consistent regulation of medical devices across Europe. The MDR has a significant effect on innovation; on the one hand, its rigour and strictness make it harder for devices to secure approval; on the other hand, once devices are approved, they have access to the entire European market.

The MDR made Mecuris international from the start, as they could automatically look outside of Germany for customers thanks to regulatory alignment across Europe. While the regulatory regime is uniform across Europe, however, the reimbursement regime is most definitely not.

'As a start-up, it really helps having one rule for the whole of the EU, because previously you had different rules for every country,' co-founder Manuel Opitz said. 'In the long-run, this could be beneficial for start-ups, and membership of the EIT really encourages us to see Europe as our playground.'



It's estimated that one million people experience limb amputations each year around the world, which equates to one every 30 seconds. Getting a prosthesis that fits is crucial, but the process can take several visits to your medical team and weeks to perform. It's an area that is seeing tremendous innovations, driven by projects such as the Cybathlon competition that emerged out of ETH Zurich to showcase developments in the field.

At the forefront of the sector is the German start-up, Mecuris, formed in 2016 by a team of six as a spin-off from the Ludwig Maximilian University Hospital Munich, and who develop software to help 3D-print custom orthotics and prosthetics in a fraction of the time currently required to craft such devices by hand.

Each product is based upon a 3D scan of the patient, which ensures a perfect fit for the wearer and allows each device to be fully customised to the individual tastes and requirements of the patient.

## A changing space

The sector has undergone considerable change in recent years with the roll out of the Medical Device Regulation (MDR) across the EU. The regulation, which came into



Website:  
<https://www.mecuris.com/?lang=en>



Twitter:  
<https://twitter.com/mecuris>



Country:  
Germany

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Where challenges still exist when breaking into overseas markets is in understanding the different reimbursement mechanisms deployed by healthcare systems across Europe. For Mecuris, this is the biggest hurdle they face today, and it's an area that consumes a lot of the attention of the team.

The aim is for the EIT Community to help navigate the various health systems across Europe and provide that smooth transition into the market. Mecuris was first exposed to the EIT ecosystem via the EIT Health Catapult, where they won the regional DACH event, before officially joining the EIT Digital innovation community, which is providing a range of support, from finance to contacts.

## Innovation engine

Mecuris is a good example of the innovative strengths of Europe as a whole. Reports such as INSEAD's Global Innovation Index highlight the strong scientific and engineering base in Europe, and start-ups such as Mecuris are a good example of this expertise being turned into innovative products and solutions. For Europe to continue to thrive, however, it's vital that this technical expertise is given the financial and commercial support it needs to turn knowledge into success in the marketplace.

'Europe can still struggle with a general aversion to risk that can hold back innovation,' Opitz said. 'It's also clear how economies like China and the United States have a largely unified reimbursement system that makes scaling medical innovations so much easier than here in Europe.'

The essence of entrepreneurship is charting your own path, however, and Opitz believes this may be what's required in Europe as the continent strives to innovate with a distinctly European flavour.

