

Welcome to our second Wednesday look at European MedTech. This week the money went into heart monitoring, hospital sensors and handheld eye imaging, the EIC picked its latest Accelerator companies, two North American companies won MDR certificates for Europe, and the Parliament's timetable for the MDR and IVDR revision slipped into January.

1. Kardi Ai raises €5.3M Series A for wearable heart rhythm monitoring

On 11 November Czech startup Kardi Ai raised €5.3 million in a Series A led by German health tech fund Callisto Health, with Česká spořitelna and Slovenská sporiteľňa (through Seed Starter), BrightCap Ventures, Purple Ventures, DEPO Ventures and Garage Angels. Its platform combines an ECG chest strap, a mobile app and AI analysis of the recordings, and it works with more than 70 hospitals in the Czech Republic and more than 6,000 users. Germany is the next priority, followed by planned entries in India, the UAE and Singapore. It matters because a Central European wearables company built a real hospital base at home before heading west.

Source: Tech.eu

2. Akara raises $5.5M for privacy friendly AI sensors in hospitals

On 11 November Dublin based Akara, a Trinity College Dublin spin-out, raised $5.5 million led by Locke Health, bringing its total funding to $12.3 million. VTC Ventures, the EIC Fund, CommonKind and NovaVector Holdings joined existing investors ACT, Atlantic Bridge and Enterprise Ireland. Its wall mounted thermal sensors, with AI running on the device, show how clinical spaces are used without capturing detailed images of patients or staff, and the technology is already in hospitals in Ireland, the UK and the US. It matters because hospital capacity, and not only new therapies, is now attracting European investment.

Source: Silicon Republic

3. Siloton wins an £8.4M Innovate UK contract for handheld retinal imaging

On 13 November it was reported that Bristol based Siloton has secured an £8.4 million ($11.1 million) two year contract from Innovate UK, through the Contracts for Innovation: Quantum Missions Primer initiative, to develop and clinically evaluate GiraffeOCT, a handheld OCT system built on a photonic chip. Trials of the in-clinic device will run with Sunderland Specialist Eye Hospital, and the York Health Economics Consortium will estimate the savings for the NHS, where nearly 623,000 patients were waiting for ophthalmology appointments at the end of July 2026. It matters because public money is helping move eye care out of the hospital and closer to home.

Source: The Ophthalmologist

4. The EIC picks 35 Accelerator companies, and DiaMonTech gets €2.5M for needle free glucose monitoring

On 16 November the European Innovation Council announced 35 start-ups and SMEs selected from 453 full applications, with €84 million in proposed grants and 32 of them to be assessed for EIC Fund equity of up to €10 million each. Health names on the list include Surgecare (France, day 1 discharge decisions after abdominal surgery), EndoGene.Bio (France, uterine diseases), THEREMIA (France, clinical intelligence in CNS) and Sia Cellboxlab (Latvia, organ-on-chip). The same day Berlin based DiaMonTech said it is receiving €2.5 million from the EIC Accelerator to build a smartphone sized prototype, the D-Pocket, that measures glucose through the skin with mid-infrared light, in an 18 month project that began on 1 October. It matters because non-dilutive EU money is still one of the few ways to fund the riskiest device work in Europe.

Source: European Innovation Council and EIC selected companies list and DiaMonTech

5. Two North American companies win CE marking under the MDR

On 17 November Dallas based Newton announced CE marking under the EU MDR for its Neurolens N3 eye alignment measurement system, issued by Intertek Medical Notified Body AB, and said it expects to reach its first European markets in 2027. On 16 November Calgary based MacuMira announced MDR CE marking, as a Class IIa device, for its microcurrent treatment for dry age-related macular degeneration, which is already used in more than 300 clinics, with more than 40,000 treatments delivered, in Canada, Australia and New Zealand. It matters because both products were helping patients elsewhere before Europe.

Source: PR Newswire (Newton) and GlobeNewswire (MacuMira)

6. Ceroflo opens a final Irish EIIS round of up to €5.5M, with trials starting in the US and Japan

On 13 November Galway based Ceroflo launched its third and final EIIS round, of up to €5.5 million with a deadline of 30 November, to support clinical trials of its SubMax intracranial stent for intracranial atherosclerotic disease (ICAD). The company has treated two patients so far and says it is starting with the US and Japan. It was founded by stroke interventionists from Karolinska University Hospital in Sweden, Singapore and the Royal London Hospital. It matters because an Irish stent company with European founders is choosing to start its clinical path outside Europe.

Source: Business Post (commercial report)

7. MDR and IVDR revision: the indicative plenary date moves to January

The European Parliament's Legislative Observatory now lists 18 January 2027 as the indicative plenary date for the first reading of the MDR and IVDR simplification proposal, procedure 2025/0404(COD). Earlier this month it showed 14 December 2026. The lead Public Health committee (SANT), with Oliver Schenk as rapporteur, has still not voted, and the file reads "Awaiting committee decision". Until Parliament and Council agree a final text and it is published, the current MDR and IVDR apply in full. It matters because every month of delay is another month under today's rules.

Source: European Parliament Legislative Observatory and Vigilo MedTech (status on 13 November)

8. EUDAMED: the device registration deadline is 28 November

Under the Commission's EUDAMED transition timeline, devices whose first units were placed on the market before mandatory use began on 28 May 2026, including legacy devices, must be registered in the UDI/Devices module by 28 November 2026 if further units are still being placed on the market. Certificates issued under the MDR and IVDR must be registered by 28 May 2027. These dates follow Commission Decision (EU) 2025/2371. It matters because ten days from now, a device missing from EUDAMED becomes a compliance problem for every manufacturer still selling it in Europe.

Source: European Commission (EUDAMED transition timeline) and EUDAPrep

Gary's take

This week two companies from North America received MDR certificates, and both were already helping patients in other countries before Europe. I keep wondering what that tells us. My honest feeling is that the MDR has gone further than it needed to, and that much of the weight it adds ends up as paperwork in Brussels rather than as safer care. Many new products never reach European patients at all, or arrive years later, and an Irish stent company starting its trials in the US and Japan is one quiet example. I am still not sure whether this is good or bad, and I understand those who say that caution protects people. But I do believe European healthcare is paying for it, and that most people have no idea. The technology world talks about this every day, yet I am not convinced that doctors, health reformers, or even the people who run the MDR can see the treatments that never arrived. With the Parliament vote now pushed into January, it feels like a good moment to ask the question openly.

When a good device reaches patients in Canada or the US before Europe, who in Europe should be asking why? You are always welcome to write to me directly, and you can find more of my articles, and book a short introductory call, at synergenmedtech.com.

Sources note: all items were found through a public web scan of about 11 to 18 November 2026 and each was checked against the linked source. Amounts and dates are as reported by the companies or the cited media. The Ceroflo item comes from a commercial report in the Business Post. No new EU HTA joint clinical assessment for a medical device and no new MDR notified body designation were found in this window.

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