Interview Focus

An Irish entrepreneur's perspective on medical device certification

> *"The MDR (Medical Devices Regulation) is a lot to take in, but the forms NSAI has developed guide you quite well through the process of getting CE marking certification."*
>
> JOHN O' DEA, CEO OF PALLIARE

NSAI

Irish medtech success in CE marking

An interview with John O' Dea, CEO of Palliare

For medical devices companies, the European Union Medical Devices Regulation (MDR), applicable since May 2021, has changed the certification landscape dramatically. "We are in a seismic shift from a regulatory standpoint," says John O'Dea, medical device industry veteran and CEO of leading Irish medtech firm Palliare.

Not only is the regulation more stringent than the previous EU Medical Device Directive (MDD), but all devices previously certified under the MDD must also now be certified under the MDR. This certification is vital for medical devices companies to ensure quality and access to international markets.

It was a landmark moment, therefore, for leading Irish medtech firm Palliare when it secured CE Mark certification under the MDR and through NSAI for its EVA15 surgical device.

CE marking signifies that products sold in the European single market meet high safety, health and environmental protection requirements. Other global markets often seek CE marking too when it comes to permitting the import of medical devices.

A landmark moment for Irish medtech

Palliare's product is one of the first of its type to meet the more extensive regulatory requirements for medical devices in Europe. Achieving the certification meant the company could access the European market immediately.

"This is an important step forward for our company," says John. *"Certifying EVA15 has entailed an extensive exercise, one that puts the company on a firm regulatory approval footing in Europe for the coming years. We have now started the process of installing EVA15 in leading robotic surgical training centres in Europe".*

Cutting-edge tools for the new surgical age

Flagged as one of the top five medical devices companies to watch in Europe in 2023, Galway-based Palliare is a trailblazer in the world of surgical devices. John co-founded the company

in 2018 as a spin-out from gastro-diagnostic company Crospon, which he had founded in 2006 and which was acquired by Medtronic in 2017.

In 2021, Palliare raised USD$8m in Series A funding for its innovative insufflator and smoke evacuation technologies.

Insufflators are used to inflate parts of the body with carbon dioxide during procedures such as laparoscopies, colorectal surgery and endoscopic surgery. This gives surgeons better visibility and more room to work.

Many of the tools used by surgeons cut by burning rather than with blades, however, meaning these tools emit hazardous smoke. As this smoke is inhaled by surgical and nursing staff, it is a workplace health issue and one that is increasingly regulated. Smoke evacuation during surgical procedures is now mandatory in 13 US states, for example.

"Our product is particularly attuned to the needs of robotic surgery," says O'Dea. *"It tends to require a higher-performance, more responsive insufflator that can adjust the levels of carbon dioxide to compensate for any leaks caused around tool entry points – these happen more in robotic surgery."*

The new challenge under MDR

To gain access to the European market, however, Palliare had to achieve CE mark certification for EVA15. As a serial medtech entrepreneur, John had frequently secured CE marks and certification to ISO standards in the past.

"We're quite experienced in the accreditation process, but the massive change in requirements under the much more demanding MDR is a huge challenge for our industry," he explains. *"The level of scrutiny has gone up fivefold and getting certified is a much more intense process."*

This means the CE mark approval cycle has become much longer and more complex, with Palliare seeing it take two years rather than three months as it would have anticipated under the old MDD system. Likewise, whereas it would have received questions on previous CE mark applications, and it received significantly more on this one.

On the other hand, says John, European patients will benefit from better incident reporting and more transparency around product failures.

Benefitting from NSAI guidance

NSAI offers a full range of services relating to management system standards and certification services for medical device manufacturers.

John chooses to seek accreditation through NSAI as he likes to "shop local" in Ireland and appreciates how approachable the organisation is as a notified body. He also says the templates and forms developed by NSAI for the CE mark accreditation process are incredibly useful.

Any medtech business applying for a CE mark under the MDR should take the time to read the actual regulation, he adds. *"Your file is going to be adjudicated word for word against it,"* he says, *"so you need to assess and understand how you comply with each clause."*

He advises any medtech company planning to seek CE marking under the MDR to prepare for a rigorous, in-depth process. *"While I continue to be a real critic of this new post-MDR world, I have had to learn,"* he says. *"Smaller companies in particular have to be aware the workload for the submission process is significant and time-consuming."*

Palliare.com

+ **As well as being designated under MDR as a notified body, NSAI is also one of only 10 notified bodies in Europe for in vitro Diagnostic Regulation 2017/746 (IVDR).**
+ **Furthermore, NSAI Inc in the US is accredited to the Medical Device Single Audit Program (MDSAP), which covers the medical device regulatory requirements for Australia, Brazil, Canada, Japan and the US. It may be provided by NSAI in conjunction with EU auditing activities.**
+ **To find out more about our work in medical devices, visit www.nsai.ie/certification/medical-devices/**

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