Brexit and the effect on the UK medical device industry

How one company has dealt with the challenge.

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For a long time the restless elephant in the room, Brexit has now turned into an angry bull, still locked down but ready to erupt and no matter which side of this now existential divide you stand on, this bull, once released will liberate vast amounts of pent up energy. For Brexiteers (supporters of Brexit) this release of energy will lead to a liberated and proud Great Britain ready to assume (or resume) its rightful place as a powerful independent nation. For remainers (in the EU) this energy is a vast waste of time and money, a collective angst of citizens who have been lied to and misled and whose exit from the EU will result in enormous personal hardship along with the nation itself which at best will take generations to heal, and at worst will lead to the break-up and catastrophic failure of the United Kingdom itself.

It is against this background that those of us in the medical device industry have needed to keep a cool head, listen to the often conflicting "official policy" statements and try to see through the political manoeuvrings in order to take mitigating action to serve our customers across Europe and maintain our businesses regardless of whatever form Brexit takes.

The European medical device industry is governed by the European Medical Device Regulations (MDR), a more extensive and stringent set regulations that were introduced in 2016 as a successor to the former Medical Device Directive (MDD). The MDR is agreed and adopted at the EU level and is administered at the national level by the Competent Authority in each EU member state and as well as those of the European Economic Area (EEA) such as Norway. The Competent Authority in the UK is the MHRA (The Medicines and Healthcare products Regulatory Agency). Unlike the FDA in the US, the Competent Authorities have no legislative power to determine a medical device manufacturer's compliance with the MDR but delegate this to so-called Notified Bodies who carry out audits, review technical files and issue the CE and other certifications. Notified bodies are registered with the national Competent Authority in the country in which they operate, but under EU level agreements a product certified by a Notified Body in any member state (and EEA country) is recognised by the Competent Authorities in all other member states and consequently may be freely sold as a medical device in all EU and EEA countries.

For UK medical device manufacturers whose products' CE status has been determined by a UK registered Notified Body, Brexit presents a problem. In principle, Britain leaves the EU on the 29th March, just a few weeks away. As of today (12th March) we don't know what form Brexit will take. If there is a "deal" Britain may remain part of the European Customs Union and it is very likely that harmonisation of standards and legislation such as the MDR will continue to operate. However a "no deal" Brexit would leave the UK outside the EU and for a medical device manufacturer, with products certified by a UK Notified Body, this could mean a sudden closing of markets in the EU.

As a world-leading digital healthcare company, we have a corporate and social responsibility to anticipate all scenarios and are currently planning for every eventuality, including a no-deal scenario. We realise the key to the success of the transition is to find ways to neutralise the threats, capitalise on any opportunities they may present, and ensure the continuity of supply of our products and services to our customers across Europe.

Isansys has created and developed the Patient Status Engine, a CE (Class IIa) and FDA (Class II) certified medical device. The PSE is a wireless remote monitoring platform intended for use by healthcare professionals for the real-time, continuous collection of physiological data of neonates, children and adults in home and healthcare settings. Established in 2010 in the UK, Isansys opened its European subsidiary Isansys GmbH in 2017 for its customers to ensure a close-working seamless, commercial partnership between an EU entity and an EU customer.

Our main focus amidst the Brexit turmoil is to ensure that our EU customers feel little or no impact from a no-deal or hard Brexit. Already the commercial contracts in continental EU countries are made with Isansys Lifecare GmbH in Germany, meaning that no VAT or similar complications will arise. We have no significant dependencies on EU wide supply chains that could be disrupted. We have built up sufficient stocks of electronic components and other materials to hedge against delays in imports most of which come from outside the EU. In the advent of a no-deal Brexit and the immediate imposition of tariffs, we intend not to pass these onto our customers and if necessary, and in the extreme, will implement mitigation measures, including the transfer of manufacturing to our German subsidiary.

To return to the regulatory challenge posed by Brexit. In 2012, Isansys secured CE certification for its first-generation monitoring platform. This cleared the PSE for use in the EU and other countries that recognise the CE Mark. For us, the CE marking of our technology formed the cornerstone for market access and further demonstrated our commitment to delivering safe, effective, reliable and clinically accurate devices. All our devices and systems are approved medical devices, ready for clinical use. We work to an accredited ISO13485: 2016 quality management system to ensure that regulatory compliance is designed in from the outset. All our products and services are assessed by our Notified Body, BSI, and certified that they comply with the MDD and (shortly) the MDR. As we have seen, a no-deal Brexit could mean that UK manufactured medical devices that are certified by a UK registered Notified Body can no longer be sold in the EU and EEA without undergoing lengthy and expensive requalification and recertification.

Recognising this risk our Notified Body, BSI has worked with its client companies to transfer their CE registrations to BSI (Netherlands), so that we now have a new Notified Body number (2797) that now appears on our certifications for sales into Europe, which for the time being includes the UK. Since this transfer was more like a copy-paste process, if the UK should not follow the EU Medical Device Regulations post Brexit, we can still use our UK BSI registration (0086) for sales into the UK.

In this way, we can ensure that our customers and their patients, wherever they are in the UK or Europe, are not put at a disadvantage and that Isansys will continue to play a leading role in promoting new directions in data driven healthcare and new generation patient monitoring – in the UK, in Europe and throughout the world.