

12/11/2020

## **Brexit Statement**

Dear Customer,

As you will know, as it currently stands, on the 31<sup>st</sup> December 2020 the Brexit transition period comes to an end and new regulatory conditions will apply to the UK and EU unless a trade deal is agreed.

This communication is to show customers the steps we have taken to ensure regulatory compliance and continued uninterrupted supply of our branded Medical Devices and distributed products.

In order to continue to sell, not only within the UK but also the EU, earlier this year we transferred to a Notified Body within the EU. We have also appointed an EU Authorised Representative and registered our appropriate products with the Competent Authority within the European Union where our EU Authorised Representative is located. Therefore, from January 1st, 2021, our products are compliant with both UK and EU requirements.

Additionally, we are adding all necessary changes, as detailed above, to our product packaging which will now be working through the supply chain. We will also be adding necessary UKCA/NI mark to our products where applicable in the timeframe given by the MHRA.

For medical devices distributed by 365/Bunzl within the UK, we are ensuring that, where relevant and in accordance with MHRA guidelines, such devices have been registered with the UK Competent Authority (MHRA) and that a UK Authorised Representative has been appointed.

If you have any questions or concerns about anything in the communication or our compliance, please contact me at any of the contact details given below.

Kind regards



### **Steve Taylor**

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