Casus Consulting

Steps to Enter the UK Market

TWO WEEKS *

1

OBTAIN PRODUCT APPROVAL

Complete UKCA Marking or EU CE Marking** process.

2

APPOINT IN-COUNTRY REPRESENTATIVE

A UK Responsible Person (UKRP) is required for non-UK based manufacturers.

3

REGISTER YOUR DEVICE WITH REGULATORY AUTHORITY

Your UKRP registers your company and devices with the Medicines and Healthcare products Regulatory Agency (MHRA). UK-based manufacturers will create an account with the MHRA and register themselves.

4

IDENTIFY IMPORTER

Your UKRP registers your Importer with the MHRA.

5

MAINTAIN COMPLIANCE

Renew the registration*** with the MHRA after one year, and then every two years thereafter.

*The timing in this chart is based upon the device already being CE or UKCA marked.

**The United Kingdom is made up of the following four countries: England, Scotland, Wales (collectively Great Britain) and Northern Ireland. Manufacturers can leverage their European CE Marking to place devices throughout the UK until 2028-2030, depending on the type of device. After that transition period ends, the requirements will be different between Great Britain and Northern Ireland. For Great Britain, manufacturers must obtain UKCA Marking in order to continue placing devices onto the market. Northern Ireland, however, will continue to require CE Marking and will not recognize UKCA marking.

UKCA Marking is separate from, but similar to CE Marking requirements. The lowest risk devices will be self-certified by the manufacturer. Meanwhile, higher risk devices will require a UKCA Marking certificate issued by a UK Approved Body. Click **this link** to our UKCA Marking webpage for more information.

***The MHRA must be notified of changes to the registration, such as updated CE Certificates.