Casus Consulting

Steps to Enter the EU Market

TWO TO FOUR WEEKS*

1

OBTAIN PRODUCT APPROVAL

Complete EU CE Marking process.

2

APPOINT IN-COUNTRY REPRESENTATIVE

An EU Authorized Representative (AR) is required for non-EU/EEA based manufacturers. The EU AR must be listed on the device label.

3

REGISTER YOUR DEVICE WITH REGULATORY AUTHORITY

Manufacturers must register their company and devices in the European Database on Medical Devices (EUDAMED).** The EU AR and national Competent Authority are involved in the company registration approval process. However, manufacturers may complete device registrations on their own.

4

IDENTIFY IMPORTER

The entity responsible for first placing products onto the EU market is the importer. The importer must identify themselves on the device label, packaging or in a document accompanying the device.

5

MAINTAIN COMPLIANCE

Maintain CE Marking. Maintain EUDAMED registration information, including provision of renewed CE certificate information, new device models and any changes to the manufacturer details, such as name or address.

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

**EUDAMED is delayed. Several EUDAMED modules are available for voluntary use, but modules are not yet mandatory. Until EUDAMED is functional, the requirements of the Directives apply, which may require notifying member states individually of devices.