Casus Consulting

Steps to Enter the Swiss Market

TWO WEEKS *

1

OBTAIN PRODUCT APPROVAL

Complete EU CE Marking process.

2

APPOINT IN-COUNTRY REPRESENTATIVE**

A Swiss Authorized Representative (AR) is required for non-Swiss based manufacturers and must be identified on the device labeling.

3

REGISTER YOUR DEVICE WITH REGULATORY AUTHORITY

Only a limited number of devices currently require registration with Swissmedic. **Click this link** for additional information.

4

IDENTIFY IMPORTER

The importer must register with Swissmedic as an economic operator and be identified on the device, its packaging or in a document accompanying the device.*** The importer is responsible for both activities.

5

MAINTAIN COMPLIANCE

There is currently no registration renewal required in Switzerland.

*The timing in this chart is based upon the device already being CE marked. While the Mutual Recognition Agreement (MRA) between Switzerland and the EU has lapsed for medical devices & IVDs, Switzerland still requires CE Marking. Devices which require Notified Body review may be assessed by a Swiss or EU Notified Body.

**There is a grace period to appoint a Swiss AR. The deadlines are:

- Class IIb implantable, class III, and AIMD - 31 December 2021
- All other class IIb (non-implantable), class IIa - 31 March 2022
- Class I, systems and procedure packs - 31 July 2022
- Class D IVDs – 31 December 2022
- Class C, B IVDs – 31 March 2023
- Class A IVDs – 31 July 2023

***Per **Swissmedic's information sheet** on Obligations of Economic Opertors, the "document accompanying the device" can be affixed to or be separate from the device. Examples include: delivery note, customs documents, invoice, a sticker on the packaging or the instructions for use. Such documents must accompany the devices through the supply chain so that distributors are ableto fulfil their verification obligations, but do not necessarily need to reach the end user.