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 process in Switzerland. However, manufacturers and Swiss ARs should update Swissmedic to any changes to the Mandate, such as adding new products into the scope of the AR service.

*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

***There is, however, a grace period by which the importer must be identified with the device:

- MDR CE Marked - 26 May 2021
- MDD/AIMDD CE Marked – 31 July 2022
- IVDD/IVDR CE Marked – 26 May 2022