ISS
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

Last Minute Aid

Export to EU without MRA
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Disclaimer
The views and opinions expressed in the following presentation are those of the author.

Abbreviations

LM = Legal Manufacturer
EAR = European Authorised Representative
SAR = Swiss Authorised Representative
TPA = Therapeutic Product Act
MedDO = Medical Devices Ordinance
SRN = Single Registration Number
T&M = Time and Material
TD = Technical Documentation

Assumptions

- **The MDR will be valid in Europe as of 26 May 2021**
- **Switzerland adopts the MDR rules with the new TPA and MedDO**
- **European Commission keeps its long know position:**
  - Swiss legislation is not recognised as equivalent by the EU without an adapted MRA
  - The MRA does not cover MDR
  - MRA is not longer applicable to MDD as MDD is replaced by the MDR
- **Switzerland will have third country status as of 26 May 2021**

1. Which companies are affected?

Two groups are affected:

1. Swiss manufactures (LM for Europe in Switzerland)
2. Outside of Europe manufactures with basis in Switzerland (LM for Europe in Switzerland)

The implications are similar:

- Both need an EAR (within EU27) in order to sell their products in the European market
- Both may use their Swiss Site as SAR in order to sell their products on the Swiss market*
    - A transition time for the SAR is expected
    - As with the EAR the SAR responsibility can be outsourced to a service provider**

* This webinar is focussing on Swiss export to Europe, SAR specific questions can be addressed during specific SAR-webinars hosted by Swiss Medtech
** e.g. www.swiss-rep.ch

2. Manufacturers of Class I

MD Class I
(MDD)

Stay Class I (MDR)

After 26th of May 2021:

Products need to be in compliance with MDR.
Swissmedic notification possible but probably not valid.

Therefore you need to **choose your LM/EAR within EU27** and to make a **notification to the responsible CA.**

Up classified incl. Ir (MDR)
Ref.: MDCG 2020-2 rev.1

MDR Art.120
(grace period)
but LM/EAR needed!

Be careful about significant changes

Eudamed obligations

Eudamed notification to be performed **by manufacturer**
Practical **guidance missing** (unknown)

3. Manufacturers above Class I

- **To be legally compliant, you need your LM/EAR within EU27**
  - You need a good TD in order to be accepted by an EAR
  - Several Solutions and Service Providers offer their services*
- **Eudamed notification is still voluntary and has to be performed the manufacturer**
  - If you want to make a voluntary notification, you need a country that provides a SRN
- **What needs to be on the "Labelling"?**
  - Manufacturer, EAR in case the manufacturer is not LM within EU27, Importer**

* e.g. https://www.iss-ag.ch/download_center/factsheets/en/Factsheet_PlanB_@_EAR_en.pdf

** The importer himself must label the products (or their packaging) with his details. This includes the importer's name, trade name/trademark, establishment and address. Alternatively, this information may also be provided on a document accompanying the product. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. EAR Costs

Topic	Cost	Remark
Initial review of TD	T&M basis	EAR needs full access to TD
Yearly basic fee	2 – 8k€ / family	Is risk class depending Family e.g. according to GMDN
Maintain Eudamed	~ 150€ / change	With some providers included in the basic fee
Vigilance	T&M basis Up to 260€/h	The topic with the highest risk for surprises
Insurance	???	Some are requiring the LM's insurance company to cover EAR's risks