

Last Minute Aid

Export to EU without MRA 7th of April 2021

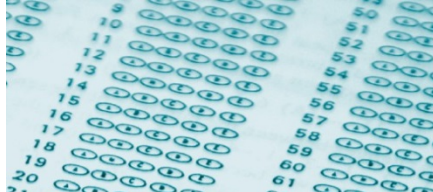
Bernhard Bichsel, Strategic Business Developer, Senior Consultant
bernhard.bichsel@iss-ag.ch

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Abbreviations

LM = Legal Manufacturer

EAR = European Authorised Representative

SAR = Swiss Authorised Representative

TPA = Therapeutic Product Act

MedDO = Medical Devices Ordinance

SRN = Single Registration Number

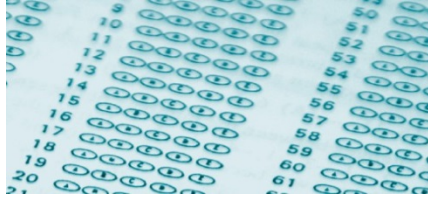
T&M = Time and Material

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:

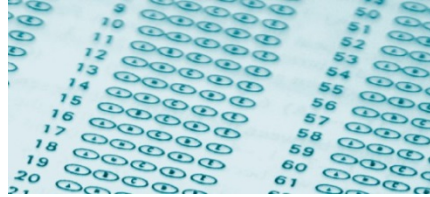
1. Swiss manufactures (LM for Europe in Switzerland)
2. Outside of Europe manufactures with basis in Switzerland (LM for Europe in Switzerland)

The implications are similar:

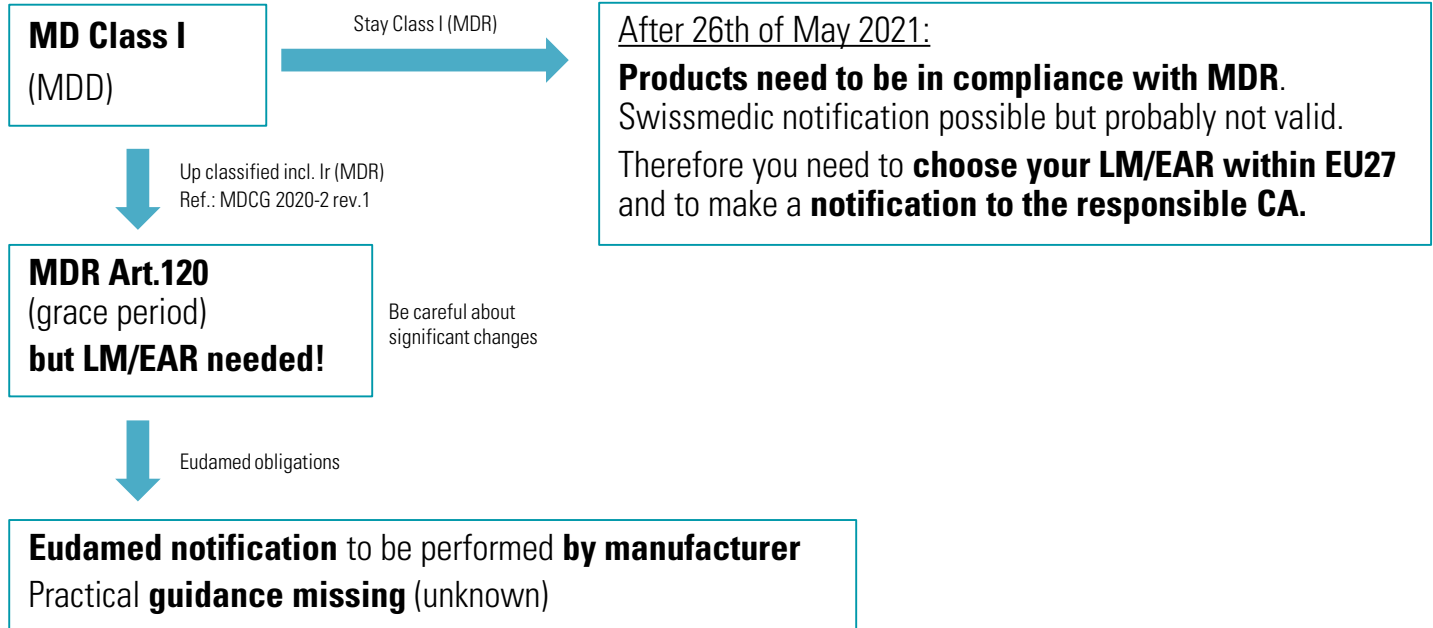
- Both need an EAR (within EU27) in order to sell their products in the European market
- Both may use their Swiss Site as SAR in order to sell their products on the Swiss market*
 - A transition time for the SAR is expected
 - As with the EAR the SAR responsibility can be outsourced to a service provider**

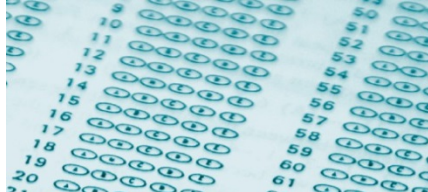
* This webinar is focussing on Swiss export to Europe, SAR specific questions can be addressed during specific SAR-webinars hosted by Swiss Medtech

** e.g. www.swiss-rep.ch



2. Manufacturers of Class I



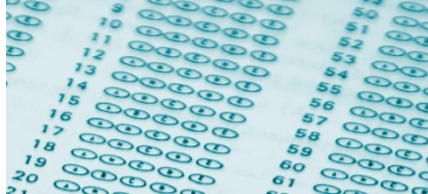


3. Manufacturers above Class I

- **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