Direct marking UDI-DI registration in Eudamed: 2 options, which one to choose?

You can have two options to register UDI-DI for direct marking in Eudamed depending on which rules and constraints you want to apply and type of flexibility you would allow.

The two options are:

- 1) you consider the direct marking UDI-DI as a kind of unit of use DI and therefore you register it the same way as a unit of use DI. It means that for a first level UDI-DI registration you provide as an attribute attached to it the direct marking UDI-DI if applicable. It is the option chosen by the US FDA;

- 2) you consider the direct marking UDI-DI as a first level UDI-DI and therefore you register it as such and you flag it as a UDI-DI for direct marking. It does not mean that the direct marking UDI-DI and the UDI-DI of base package are the same, it means that the base package UDI-DI is then a package DI associated to the direct marking UDI-DI. It is what we have for the time being in Eudamed.

The first essential rule to consider is that you cannot have the same UDI-DI that is used for identifying different products, meaning the same UDI-DI should not be assigned for different direct marking UDI-DI and/or for a direct marking UDI-DI and a package level for the same device.

Furthermore, we have to consider what rules should be applied in case of products that could be provided sterile or not, and what is the flexibility you may have for packaging.

In the option 1, because the direct marking UDI-DI is not at first level you could imagine to have the same direct marking UDI-DI that is used for both the sterile and the non-sterile product and that you have several base package UDI-DI referencing the same direct marking UDI-DI (packaging flexibility).

In the option 2, because the direct marking UDI-DI is a first level one, you cannot have another one registered in the system. Therefore, if one would be in sterile conditions (necessarily in a package) and another one not in sterile conditions (not necessarily in a package), you shall have always 2 different direct marking UDI-DI (one for the sterile, one for the non-sterile) and the UDI-DI of the sterilised (or not) package will be always different from the direct marking UDI-DI and registered as a package DI of the direct marking UDI-DI. It means as well that the flexibility for the packaging could be only done through higher package level since you can have only one package UDI-DI for a lower level. A direct marking UDI-DI will be always with quantity 1, the first higher packaging level must be unique with only one quantity.

At the end, it is really a choice because even if the first option seems to be more flexible and therefore allows more things for packaging (and it would guarantee harmonisation with the US system), you could apply some extra rules to make it as strict as the second option, which is clearly more strict since some constraints are directly applied on the way to register the direct marking UDI-DI.

However, it seems there is still one thing you can do with option 2 that you cannot do with option 1: to have just a direct marking UDI-DI for a device and no other UDI-DI (is it possible, especially in a context of waste limitation?).

The choice of the option will determine if we consider the direct marking UDI-DI as a first level UDI-DI on its own and with the possibility to have only a direct marking UDI-DI for a device (option 2) or as rather a kind of unit of use DI (option 1).