What is MDR?
MDR is the new European Union Medical Device Regulation (EU MDR (EU) No. 2017/745) that replaces the MDD regulation (Council Directive 93/42/EEC).

When will MDR come into force?
MDR came into force in 2021, however it will be applied in total in 2028.
The European Union was not ready to apply the whole of the new regulation and subsequently granted several extensions, the last of which will end on 31/12/2028 for class IIb products and on 31/12/2027 for class III products.

Which Medical Devices are legally in circulation today?
1. Medical Devices that have been certified according to MDR.
2. Medical Devices whose CE (MDD 93/42) has expired but have received the Confirmation Letter from an NB that confirms that the MDR Certification process for their products has started. (Medipac's case)
3. Medical Devices that were produced under an active CE (MDD), they have not received the Confirmation Letter but the products have not expired yet.

What has been done by Medipac?
- Medipac has already initiated all processes towards complying with the new European regulatory framework.
- The amendment of the technical files, internal procedures, etc. is currently in progress.
- Medipac has been implementing all the necessary product marking requirements for the last 3 years, following the new regulations (Datamatrix, UDI Label).
- In this light, Medipac has already published the Confirmation Letter relating to the compliance to the new MDR rules in collaboration with HTCert. Thereby, all new products will have the CE marking of the new Notified Body, which is CE2803.
- Shortly, we are going to be granted the first certificates concerning a specific group of suture categories whereas the process in relation to the rest will have been completed by the next few months.

Can I sell and use Medipac products under CE0653 and, if so, until when?
All products manufactured by Medipac under the previous regime (MDD /CE0653) circulate legally in the market and can be used up until their expiration date, according to their IFU.

Would it be preferable to wait until all Medipac products get MDR-certified?
There is no reason for which someone must wait for the MDR certification, since all products that are being produced by Medipac are in accordance with MDR (article 120) and its requirements (Confirmation Letter by Notified Body).