

-	CLASS	SOURCE	PRODUCT IMPACT
CE MARKING	Class I	Article 123.2	Must be compliant to Regulation from the <b>26 May 2021</b>
	Class I under Directive and changed under Regulation	Article 120.3	Declaration of conformity may still be used until <b>25 May 2021</b>
	Medical Device for which the conformity assessment procedure involves a notified body	Article 120.2	Certificate in accordance with Directive 93/42/EEC <b>issued prior to 25 May 2017</b> --> Remains valid until the end of the period indicated on the certificate, EXCEPT FOR certificates issued in accordance Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022
			Certificate in accordance with Directive 93/42/EEC <b>issued from 25 May 2017</b> --> Remains valid until the end of the period indicated on the certificate (under the 5-year maximum). <b>They shall become void at the latest on 27 May 2024</b>
PLACED ON THE MARKET/PUT INTO SERVICE	Class I	May be placed on the market as long as the CE marking is valid. i.e. for products compliant with Directive 93/42/EEC until 26 May 2021	
	Class I under Directive and changed under Regulation	Article 120.3	<b>No change</b> , possibility to place on the market or put into service until 26 May 2024 (As long as, there are no significant changes, for a declaration drawn up prior to 26 May 2021 and product continues to comply with the Directive)
	Medical Device for which the conformity assessment procedure involves of a notified body		May be placed on the market as long as the CE marking is valid. i.e. for products compliant with Directive 93/42/EEC until the end of the period indicated on the certificate, so at the latest the 26 May 2024. (As long as, there are no significant changes and product continues to comply with the Directive)
MADE AVAILABLE ON THE MARKET/ PUT INTO SERVICE	All classes	Article 120.4	<b>No change</b> , devices lawfully placed on the market pursuant to Directive 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to Article 120.3, may continue to be made available on the market or put into service until 26 May 2025

Given that every device and registration will have its unique issues to consider companies should seek professional advice before making decisions on registration, marketing, or investment.