

Publication date: May 21, 2020

The AEMPS extends the deadline until May 25, 2021 for the adequacy of the labeling and instructions for use of medical devices as a consequence of the changes made by Brexit.

On February 1, 2020 the United Kingdom ceased to be considered an EU Member State to become a third country, as contained in the Withdrawal Agreement, ratified by the European Parliament.

From this date a transition period comes into effect that will last until December 31, allowing, for practical purposes, everything to remain the same for medical device companies in both the European Union and the United Kingdom.

In November 2019, the informative note <u>PS, 29/2019 was published</u> establishing a deadline until June 30, 2020 for the adequacy of the labeling and instructions for use of medical devices as a result of changes made amid Brexit.

Given the difficulty that this change is causing to companies and considering the consequences of the COVID-19 pandemic, which may have made its implementation difficult, the AEMPS has considered extending the deadline until May 25, 2021, in order to get companies more time to adapt labels and instructions for use of the products to the changes produced.

All relevant information is updated and developed in detail on the AEMPS website.