

Date: 26/04/2020

To Whom it may concern

SUBJECT: Change of date of application of Regulation (EU) 2017/745 on medical devices

In view of the COVID-19 epidemic and the associated public health crisis, its epidemiological development, as well as the additional resources required by Member States, health institutions, economic operators and other stakeholders, and given the health circumstances requiring significant additional resources, it would not have been possible to ensure the proper implementation and application of this Regulation by 26/05/2020, therefore, the European Parliament and the Council of the European Union considered it appropriate to postpone the application of Regulation (EU) 2017/745 by one year.

The updated date of this Regulation is 26/05/2021 and entered into force on 24/04/2020, the date of its publication in the Official Journal of the European Union (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0561&from=EN>).

Our technicians are at your disposal to support you in the transition, carrying out the appropriate checks and planning from now on the updating of the technical documentation in accordance with the new Regulation

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BEST REGARDS
BIOTECO S.R.L.