



**MAR. 23** 

## INFORMATIV NOT

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS** 

## Amendments to the frequency of full reassessments regarding MDR and IVDR

On 8 March 2023, Commission Delegated Regulations (EU) 2023/502 and 503, both dated l December 2022, were published.

Delegated Regulation (EU) 2023/502 amends **Regulation (EU) 2017/745** of 5 April 2017 ("MDR") on medical devices, while Delegated Regulation (EU) 2023/503 amends Regulation (EU) 2017/746 of 5 April 2017 ("IVDR") on in vitro diagnostic medical devices.

The changes made concern the frequency of full reassessments of notified bodies. As originally drafted, a complete re-assessment was mandatory three years after the notification of a notified body

The European Commission has taken this measure following serious difficulties in the certification of medical devices during the transitional periods of the new regulations.

and every four years thereafter. With the entry into force of the new regulations, this will only become mandatory five years after the notification of a notified body and every five years thereafter.

The European Commission has taken this measure following serious difficulties in the certification of medical devices during the transitional periods of the new regulations, taking into account the limited number and capacity of notified bodies. However, full re-evaluations started before 11 March 2023 should continue in order to optimise the use of resources already invested.

Both Regulations will enter into force on 11 March 2023.

In this context, the European Commission had already announced on 6 January 2023 a proposal for a legislative amendment aimed at extending the transition periods provided for in the MDR and the IVDR, as explained <u>in this Informative Note.</u> ■

Eduardo Nogueira Pinto Eliana Bernardo Ricardo Rocha Rita Antunes da Cunha

Healthcare Life Sciences & Pharmaceuticals

PLMJ COLAB ANGOLA - CAPE VERDE - CHINA/MACAO - GUINEA-BISSAU - MOZAMBIQUE - PORTUGAL - SÃO TOMÉ AND PRÍNCIPE - TIMOR-LESTE

This document is intended for general distribution to clients and colleagues, and the information contained in it is provided as a general and abstract overview. It should not be used as a basis on which to make decisions and professional legal advice should be sought for specific cases. The contents of this document may not be reproduced, in whole or in part, without the express consent of the author. If you require any further information on this topic, please contact Eduardo Nogueira Pinto (eduardo.nogueirapinto@plmj.pt).

1/1. Transformative Legal Experts www.plmj.com