Ministerie van Volksgezondheid,
Welzijn en Sport

Notification

Cessation of the MRA between Switzerland and EU

Consequences for the Dutch medical device market

The European Commission announced that the Mutual Recognition Agreement (MRA) for medical devices between Switzerland and the European Union ceased to apply on 26 May 2021.

Dutch Ministry of Health, Welfare and Sport (VWS) follows EU rules

The Dutch Ministry of Health, Welfare and Sport follows the announcement of the European Commission and expects Swiss manufacturers to designate an authorised representative in the EU. However, we understand if the labelling of products in stock is not yet adapted to this new construction. Therefore, the Ministry allows manufacturers during a period of 6 months (until November 26, 2021) to sell out these products.

Tolerance period for non-conformity in labelling of medical devices in stock

In these specific cases and during this specific period, the Dutch Health and Youth Care inspectorate will not take action on this non-conformity. Manufacturers still have to fulfil all the other legal requirements. The Dutch Health and Youth Care inspectorate will take measures if necessary.

Other non-conformities not tolerated

Meanwhile, the Dutch inspectorate will take action in other cases when non-conformities are determined related to the cessation of the MRA. For example, in case that Swiss manufacturers have not designated an authorised representative in the EU while providing medical devices to the Dutch market. Or, in case a Dutch manufacturer with a Swiss Notified Body has not transposed its activities to a Notified Body located in the EU.

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