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Medical devices: a joint statement to strengthen governance and coordination of the EU regulatory framework

RÉFÉRENTIELS - RÉGLEMENTATION

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The competent authorities of several Member States, including ANSM, approved a consensus statement on the reform of the EU regulatory framework for medical devices. Shared with the European Commission, the statement underlines the urgent need to address the topics of governance and centralisation.

On June 24th, national competent authorities, together with representatives of the European Commission attending as observers, met in a workshop in Utrecht (Netherlands). Their objective was to discuss ways to make the EU regulatory framework, described under the current Medical Devices and In-vitro diagnostics Regulation, function in a more consistent, harmonised, and effective manner.

Through this consensus statement, the authorities acknowledge the significant work undertaken by the European Commission and reaffirm their support for this work in addressing identified short and medium term priorities.

At the same time, the authorities call on the need for a detailed plan and a resource assessment to support the evolution of the governance model. They call on the European Commission to carry out a thorough analysis of the provisions related to governance and coordination, to strengthen and adapt them, while fully considering the role that centralisation could play in the future regulatory system.

Read the consensus statement (23/07/2025)