P9_TA(2021)0498

Transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices


(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2021)0627),

– having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0381/2021),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 8 December 2021¹,

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 24 November 2021 to approve Parliament’s position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

¹ Not yet published in the Official Journal.
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2022/112.)